AIDS and the Public Debate

CAROLINE HANNAWAY
Editor-in-chief
VICTORIA A. HARDEN
Editor
JOHN PARASCANDOLA
Editor

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Historical and Contemporary Perspectives

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Contents

Preface

The editors wish to acknowledge with gratitude the contributions of many people and organizations that made this volume possible. The initial proposal for such a book was put forward at the 1992 meeting of the AIDS History Group of the American Association for the History of Medicine by William H. Helfand, who, with his wife Audrey, manifested their interest tangibly by taking on much of the logistical management of the conference that stimulated production of the book. Financial support for the conference was generously provided by Merck & Co., Inc. and Hoffmann-La Roche, Inc. as patrons, and by SmithKline Beecham Pharmaceuticals and the Upjohn Company as contributors. The National Library of Medicine and the National Museum of Health and Medicine provided meeting space and support. The following individuals contributed to the conference and provided encouragement in bringing out the book: Robert A. Whitney, Deputy Surgeon General, Public Health Service; Ruth L. Kirschstein, Acting Director, National Institutes of Health; Donald A. B. Lindberg, Director, National Library of Medicine; Arthur J. Lawrence, Acting Director, National AIDS Program Office, Public Health Service; Kristine Gebbie, National AIDS Policy Coordinator; and Richard J. Levinson, Director of Public Affairs, National Museum of Health and Medicine.

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Introduction

AIDS has had a history of little more than a decade, but its impact on society has been so significant and its effects so diverse that it is not too early to begin to analyze the ways in which this disease has shaped our world and our reactions to it. Indeed, this is not the first book to attempt such an analysis. The unique feature of this volume, and the conference on which it is based, is that it brings together two very different and complementary perspectives. Some of the contributions are by physicians and scientists who have been and still are participating in AIDS research and the making of AIDS policy. For example, former Surgeon General C. Everett Koop, Anthony S. Fauci of the National Institutes of Health, and James W. Curran of the Centers for Disease Control and Prevention provide personal accounts of these developments. Other contributions are from historians and social scientists, who reflect on their subjects from a more impersonal viewpoint, using the analytical tools of their crafts. The division, of course, is not always completely clear-cut, as exemplified by the papers of Paul Farmer and Maryinez Lyons, who may write as historians/social scientists, but who also have had first-hand experience of the situations they discuss. One might, in fact, argue that we have all been participants to some extent in the unfolding AIDS drama.

This book explores a variety of themes related to AIDS and the public debate over the disease. One of the subjects that necessarily receives significant attention is the role of the United States federal public health bureaucracy in the AIDS crisis and the impact that the epidemic has had on the agencies involved. The Public Health Service (PHS), housed within the Department of Health and Human Services (DHHS), has had the primary responsibility for responding to the AIDS epidemic, and several papers discuss the contributions of the PHS in the fight against AIDS.

The three PHS agencies at the forefront of the crisis were the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). The CDC played a central role in establishing how the disease was transmitted and in tracking the epidemic. NIH scientists were codiscoverers of the HIV virus, developed a test for detecting the virus in blood, and designed and implemented clinical trials on drugs such as AZT (Azidothymidine). The FDA developed policies to safeguard the blood supply, modified regulations to speed up the evaluation of therapeutic agents for AIDS, and led the fight against AIDS quackery. At the same time, the PHS Surgeon General crusaded to educate the American public about AIDS.

Several papers, however, make it clear that the efforts of the PHS (which June Osborn calls "diligent and sometimes heroic") were hampered by lack of support at the top levels of the Reagan Administration. Politics as well as science dictated the government's response at various stages. AIDS was not viewed solely as a medical issue, but was enmeshed with moral

concerns involving sexuality, substance abuse, and other controversial matters. President Reagan himself was slow to speak out about the AIDS crisis, thus failing to provide the leadership for which the situation called. Sometimes there was active interference with the work of health officials. Former Surgeon General Koop, for example, reveals that for some three years he was prevented from speaking out on the subject of AIDS by those he refers to as "political meddlers" in the White House. Koop complains that there were those in government who "placed conservative ideology above saving human lives."

As Allan M. Brandt reminds us, "disease is not merely biological, but it is shaped by behavioral, social, cultural, and political forces." The papers in this volume amply demonstrate the ways in which a variety of forces have influenced our understanding of and our reaction to AIDS. They also show that AIDS in turn has had a significant impact on public policy and social institutions. The disease has made itself felt in science, politics, and the arts. In the words of Anthony Fauci, "AIDS has had an extraordinary and historical impact on the manner in which scientists, health care providers, government administrators and regulators, and constituency groups interact."

Fauci also points out that it has proved impossible to separate HIV science from HIV policy. The AIDS debate has transformed the process of lobbying for research funds for a particular purpose. The success of AIDS activists in obtaining more government funding for AIDS research and in affecting the design of clinical trials for AIDS drugs has encouraged those concerned with other diseases (e.g., breast cancer) to take a more activist approach in their demands. The AIDS crisis has also raised anew, as Victoria Harden notes, the debate over targeted, centrally-directed research versus a more traditional reliance on basic research directed by individual investigators. Some have complained that AIDS has skewed our research priorities. At the National Institute for Allergy and Infectious Diseases (NIAID), for example, budget estimates show that funding for AIDS research equals or exceeds funding for all other NIAID research combined.

Pressure from AIDS activists has stimulated the FDA to speed up the process of review and approval of new AIDS drugs. As James Harvey Young demonstrates, however, the FDA has also had to concern itself with a host of quack therapies for AIDS. Young quotes one commentator who observed that practically "every piece of snake oil that's ever been used for anything" is being adapted for use against AIDS. Those desperately seeking a cure for their disease are often willing to try anything, and do not always appreciate what they consider to be FDA interference with their right to choose their own therapy.

R. Gordon Douglas Jr., calls our attention to the important role that industry plays in the discovery, manufacture, and distribution of drugs. The pharmaceutical industry, like academic and government laboratories, has been devoting significant attention to AIDS research, in the hopes of finding a cure and/or a preventive vaccine. But the HIV virus is a formidable foe, and its ability to mutate rapidly makes the development of drugs and vaccines against the virus especially problematic. The creation of an unusual consortium of fifteen pharmaceutical companies which will pool their efforts in the field of AIDS research is therefore a hopeful development in the fight against the disease.

AIDS has also made its mark on the scientific literature. Ruth Kulstad discusses how the first AIDS research papers were published in *Science* in May of 1983. The journal was soon receiving several papers a month on the subject, increasing to perhaps several a week by late 1984. Editorial and decision-making procedures were affected by the proliferation of work on the disease. Before long there were whole journals devoted to AIDS research, and the explosion of publications on the subject led the National Library of Medicine to issue a periodic bibliography and establish a database devoted to AIDS literature.

Another legacy of the AIDS epidemic has been a forceful reminder that science and medicine have by no means conquered infectious disease. Coupled with the discovery of the so-called "emerging viruses," such as those that cause Ebola and Marburg fever, AIDS has directed renewed attention to the field of infectious disease. Victoria Harden points out that funding for biomedical research at the NIH was dominated by chronic diseases at the time that the AIDS epidemic was beginning. Only one NIH institute, the National Institute of Allergy and Infectious Diseases, was partially dedicated to the study of infectious diseases. By 1990, however, virtually all of the institutes had established AIDS research programs.

As has already been noted, the science of AIDS cannot be completely separated from the politics of AIDS. James Curran argues that in order to prevent HIV infection, we have to confront social problems such as homelessness, poverty, prostitution, and substance abuse. The National Commission on AIDS, whose work June Osborn discusses, attempted to deal with this nexus of issues in the series of reports that it issued. In addition to the Commission's overall report, there were specific reports on such topics as the relationship of AIDS to substance abuse, the problem of HIV infection in correctional facilities, and the challenge of HIV/AIDS in communities of color.

Mark Smith specifically addresses the question of AIDS and minorities in the present volume. AIDS disproportionately affects African Americans and Hispanics, and is already the leading cause of death among males aged 25-44 in these two populations. Smith points out many of the myths and prejudices that affect our views of AIDS in minority communities, and suggests what must be done to reach out to populations which were medically underserved even before the AIDS epidemic.

We can only speculate how the initial reaction to the disease might have differed had it not first surfaced among gay men, another group that suffered the effects of discrimination. The gay community came to play an important role in the campaign to educate people about the disease and to obtain more support for research and treatment. Eventually a wide variety of community organizations, not all of them gay-oriented, evolved to assist with various aspects of the battle against AIDS. Richard Goldstein indicates how gays and others in the arts have contributed to the task of coming to terms with the personal and cultural losses occasioned by the epidemic.

As fear of AIDS gripped the nation, public reaction was not always rational, and not necessarily sympathetic to those suffering from the disease. Several authors remind us of the early calls in the United States for detention and quarantine of those with AIDS. C. Everett Koop discusses the battle over mandatory testing, a policy that he vigorously opposed. Allan Brandt argues that one of the greatest victories in public policy during the first decade of the epidemic was the prevention of draconian and ineffective measures, such as quarantine of those infected with HIV. Although such extreme steps were avoided, discrimination against those with AIDS is still a problem as Paul Farmer shows.

According to Brandt, the AIDS epidemic has forced historians to reevaluate a whole series of questions about medical and cultural responses to disease in the past. AIDS has also reemphasized the value of historical studies of public policy as it relates to disease. Such studies can help to clarify the range of options open to policy makers and shed light on the nature of the varied forces that either promote or inhibit effective policies.

The world of the arts has also not been unaffected by AIDS, as Richard Goldstein eloquently reminds us. Mortality from AIDS has devastated the worlds of literature, the visual arts, theater, and dance. Breaking with the traditional custom of ignoring the existence of epidemics, American writers, artists, and performers increasingly incorporate AIDS into their work. By discussing and depicting the consequences of AIDS, the arts help to counter

fear and stigmatization, aid in the coming to terms with sexuality, and allow expression of grief. As Goldstein concludes, how else can we face the death of the young, as well as the failure of science to save and of religion to explain.

Although this volume emphasizes the AIDS epidemic in the United States, several papers do consider aspects of AIDS in other countries. The issue of quarantine was not only of concern in the continental United States, but also at the American military base at Guantánamo on the island of Cuba. Paul Farmer examines the plight of HIV-positive Haitian refugees detained in segregated conditions of considerable privation at Guantánamo by what has been portrayed as "misguided public health initiatives." Although eligible for political asylum in the United States, a number of Haitians were denied entry by the Immigration and Naturalization Service after mandatory mass screening of all refugees revealed some were HIV-positive. Besides calling attention to the issues surrounding the status of Haitians as refugees, this instance of enforced quarantine, as Farmer indicates, demonstrates the larger effects of disease on law and politics.

Further afield in Europe, the effects of AIDS on social and political institutions and the medical profession in different national contexts are brought out in papers by Virginia Berridge and Anne Marie Moulin. In assessing voluntarism and AIDS in Great Britain, Berridge shows how small group self-help mobilization against the disease, particularly in the gay community, evolved into larger scale interaction between the AIDS voluntary sector and the British government. After AIDS became a matter of widespread concern in 1986 and a clear political priority, national rather than local initiatives gained ground and government funding affected provision of services and care. AIDS demonstrates the complexity of the interaction between voluntarism and the state.

In France, as Anne Marie Moulin explains, a combination of pride in national identity, medical arrogance, political blindness, and commercial considerations contributed to the spread of AIDS by blood transfusion, particularly amongst hemophiliacs. Short-term consequences included not only the disease and death of those infected, but also the unprecedented putting on trial of four doctors as responsible for the blood contamination. In the wake of the tragedy, the French blood transfusion system was entirely transformed. Longer-term consequences include loss of status for the medical profession, suspicion of medical science, and questioning of the French democracy's political choices. As elsewhere, the advent of AIDS has wrought substantial change in the interaction of law, medicine, and the state.

In Africa, where AIDS is a heterosexual disease, society has been undermined in ways different from the consequences of the epidemic in Europe and America. Maryinez Lyons illuminates what is happening in one African country in her discussion of women and AIDS in Uganda. Women's inability to control their own destiny in Uganda—they are subordinate to men at every stage of their lives and their access to education and means of earning a living is very restricted—coupled with frightening rates of HIV infection, 30 to 40 percent among young urban adults of both sexes, foreshadow a deepening social and economic crisis. This is in a country already battered by famine, tyranny, and civil war. AIDS in sub-Saharan Africa is an epidemic in full cry and containing it will require drastic social reform.

The toll that AIDS has taken is already staggering. World Health Organization estimates of the number of people infected with HIV are over 17 million, of which more than 4 million have developed AIDS. As James Curran emphasizes, we need to realize that the epidemic is still at its beginning. By 2000 A.D. the World Health Organization estimates that 30 to 40 million people worldwide will be infected with HIV, and over 10 million will have developed AIDS.

Yet several of the papers in this volume warn that we may be becoming complacent about AIDS. Budgets to deal with the problem are levelling off in the United States, and other health issues are occupying our attention. Allan Brandt notes that the urgency of the

epidemic has been diminished as AIDS has become "routinized" in America. He quotes the views of a colleague who fears that AIDS will be accepted as an "affordable epidemic" with "tolerable levels" of wastage. The primary reason for this concern is that it is "socially marginalized groups" who have been most impacted by the AIDS epidemic, and society already tolerates other serious problems as "normal conditions" for such populations.

Given the devastation that the disease has already caused, and the predictions for the extent of future morbidity and mortality, we can hardly afford to become complacent about AIDS. Some would argue that if we had taken more prompt and decisive action against the epidemic in the first place, we might have controlled it better. Although we cannot go back in time and change the way we have responded to AIDS, we can examine the past for lessons that may serve us in the future. A knowledge of the history of AIDS will not enable us to predict the future of the epidemic with accuracy, but it will provide us with a better understanding of the ways in which our view of the disease and our reaction to it have been shaped by our values and our institutions. Let us hope that such an understanding will assist us in charting the course with respect to AIDS into the twenty-first century.

Part I

AIDS and the United States Public Health Service

The Early Days of AIDS as I Remember Them

C. Everett Koop

Early in 1981, when I was designated as Surgeon General of the United States, I had never heard of AIDS. No one had ever heard of AIDS. As a matter of fact, there were only a handful of scientists who understood anything about immunodeficiency, and they did not have a name for it, much less know what it really was.

AIDS entered the consciousness of the Public Health Service (PHS) rather quietly, rather gradually, and with almost no fanfare at all. In June of 1981 the beginnings of what was to become the AIDS epidemic were reported at one of the senior staff meetings at the PHS, and it is now a familiar story. It was the story of those five homosexual males who developed *Pneumocystis carinii* pneumonia (PCP), a disease I had handled in my work with cancer patients at the Children's Hospital of Philadelphia. Five cases is not many, but for that disease (PCP), only a handful sounds like an epidemic, and so it turned out to be. Soon the reports began to trickle in about other cases elsewhere, and a month later, at an agency heads' meeting in the Humphrey Building in Washington, D.C., we had the second report from the Centers for Disease Control (CDC) concerning twenty-six young homosexual men recently diagnosed as having Kaposi's sarcoma. Twenty-six cases in one report, and in my lifetime I had seen but two. There was something very uncommon going on.

But from that very small beginning, those cases mushroomed into the AIDS epidemic of the late 1980s. I remember the very first thought that I had after that second presentation, and that was about sodomy and enforced sodomy in prisons. I remember mentioning this at the time, but I did not seem to find any of my colleagues thinking along similar lines.

The Public Health Service had never had experience with a syndrome quite like AIDS before, and so they gave it a somewhat awkward title, Acquired Immune Deficiency Syndrome, which we still have. For a short time some people called it "GRID," Gay-Related Immunodeficiency, but then new cases came up in non-homosexuals and so it was called A.I.D.S. And then it was just called AIDS. I have often thought what a great thing this change was because we have not had to put all those periods in the name over all these years. They could have stretched from here to the sun and back.

By August of 1981, I and others were paying attention to the unusual news from the CDC, and learned that there were now just over 100 cases and that almost half of those affected had died. So I knew—everyone knew—that we were in for big trouble, but there was not much that I could do about it. I was not yet the Surgeon General of the United States. All through that awful summer of 1981, I was preoccupied by my long struggle for confirmation as Surgeon General by the Senate. But I realized that if ever there were a disease made for a Surgeon General, it was AIDS. But, for reasons of intradepartmental politics, which I still do not understand to this day, I was cut off from the inner discussions about AIDS and from making any statements about AIDS for the next three and a half years. I

was told that I would have my hands full and that AIDS would become someone else's responsibility.

I was confirmed as Surgeon General in November 1981, but even in those early days of my tenure as Surgeon General, I had to learn about AIDS on my own. I learned about it from the newspapers, and from internal documents of the Public Health Service, to which, of course, I had access. I also read the *Morbidity and Mortality Weekly Report* and I did have discussions with colleagues.

There were two reasons, I think, why it took awhile for public health authorities to get a handle on AIDS in the beginning. First was the relatively small number of trained clinicians and researchers who were familiar with the rare diseases which were turning up as opportunistic infections, and which were occurring in places like San Francisco, Los Angeles, Chicago, and New York. The second reason was that the first patients with those conditions were homosexual men, most of whom had patronized physicians and clinics that were more understanding of their so-called "gay lifestyle." In making that choice for care, which was quite natural, these men effectively placed themselves outside of mainstream clinical medicine and therefore they were very difficult for us to know—to reach—and, of course, to help. As a result, our first public health priority, to stop the further transmission of the AIDS virus, became needlessly mired in the homosexual politics of the early 1980s. We lost a great deal of precious time because of this, and I suspect that we lost some lives as well.

By July of 1985, the CDC had reported just under 12,000 cases of AIDS and just under 6,000 of those people had died. Then only a week later, I recall that the numbers for both the cases and the deaths had jumped by 100. The AIDS epidemic was definitely progressing, and doing so at an accelerated rate.

About that time we were introduced to the death of Rock Hudson, who was the first national figure to die of AIDS. That raised further public concern, of course, about the disease, but for the first time it captured the attention of the Reagan White House because the President, having been a former actor, was still connected with Hollywood people who were now concerned. It touched the White House only rather indirectly. It certainly did not touch it nearly as severely as I wish it might have.

Also in 1985 we developed a test to identify the presence of antibodies. We had not seen the virus, but we knew it was there because we knew about the antibodies. There were many charges of foot-dragging in those days, and they still continue in public television shows, but we learned as much about AIDS in the first six years as we had learned about polio in the previous forty. Although we acknowledged that there was much that we did not know, we had made extraordinary progress in understanding what we did know. We had identified the virus; we named it, then we renamed it. We understood the epidemiology relating to homosexual men and about the transmission of the disease through the sharing of the needles and equipment in intravenous drug abuse. We learned of homosexual practices that were hitherto barely mentioned, and we understood, perhaps for the first time, the extent of homosexual promiscuity.

As I have noted, we identified the antibodies to the virus and developed a screening test on the basis of that for the detection of these antibodies. This, in turn, made the blood supply relatively safe for transfusion. We learned how to kill the virus in the blood products and made clotting factors safe again for hemophiliacs.

But above all we were concerned about how the disease was transmitted. We learned that although the virus had been identified in several body fluids, it seemed to be transmitted only through blood and through semen. Nevertheless, researchers were very cautious. I remember, for example, that Anthony Fauci, later to direct the AIDS research at the National

Institutes of Health (NIH), insisted that we check out any study that did not seem to rule out the spread of AIDS by casual contact. But gradually a convincing body of research led us to some very important conclusions.

It was clear that, in spite of all kinds of unsubstantiated claims about mosquitoes, toilet seats, door knobs, and so on, AIDS could only be transmitted in four ways: through sexual contact; through blood contact associated with intravenous drug abuse; through pregnancy or delivery—contact between an AIDS-infected mother and her infant; and finally through transfused blood. But the most important information, and perhaps the worst, and the deadliest thing, that we learned, was the news that if a person had AIDS, his or her chances of surviving the next two or three years were not very good, and of surviving much beyond that time were essentially nil.

Then, as some presidential appointees began to prepare to leave Washington after the second Reagan election, I did have the opportunity in 1984 to begin to talk about AIDS. Eventually my personal distance from AIDS information and policy came to an end when President Reagan asked me to write a report for the American people on AIDS. For the next two years, AIDS took over my life.

I had heard the rumors for a week or so and, at the end of January 1986, at a dinner hosted by then Secretary of the Treasury James Baker and his wife Susan, two members of the White House staff present came up to me and said, "You are going to be in the President's State of the Union Message," then just a few days away. They said this, but I was not too sure because White House gossip had told me that there were 1,500 items that had been presented to the President for inclusion in that speech. I thought that even if the President himself might be ready at last to talk about AIDS, I was sure that his advisors were not.

I had previously talked to the Domestic Policy Council twice about the possibility of an AIDS report, and they had raised the question with me, did I think that a Surgeon General's report would be appropriate. I said, "It would be ever so appropriate but, on the other hand, I hope you all know that there are down-sides to this politically for the President. Some of his constituents are not going to like the things that have to be said. I am not sure that you people are ready for the kind of straight talk that such a report would have to include."

The night came for the President's speech, and my wife and I sat there, in 1986, and over the tube came this rather upbeat, frothy kind of a speech. Halfway through we knew that the President was never going to mention AIDS. And he did not. That night, before I went to bed, I told my wife Betty, "I guess I am off the hook about writing that report." Then, just a few days later, the President made an unprecedented trip across town to the Humphrey Building and addressed, in the Great Hall, as many people as could crowd in there from the Department of Health and Human Services (HHS). He said all the right things. He thanked his audience for their great and faithful work and, in the course of his remarks, he said that AIDS was a top priority for the Department and he looked forward to the day when there would be a vaccine. Then he announced that he was asking the Surgeon General to prepare a special report on AIDS. That was it. There was never a formal request. I have often thought that it was a good thing I went to the speech and was paying attention.

I assumed that the report was meant to be simple and to be in language that could be understood by the average citizen; that it was meant to allay the panic of those who were afraid they might get AIDS but were never exposed to it; but it was also to warn those who were engaged in rather risky behavior what the inevitable outcome would be if they encountered the AIDS virus. But I also knew that the government clearance process could ruin any report that I might write and what I needed was the authority to write a report on my own

without having it cleared by anybody. That was a very difficult thing to achieve in this government. What made it possible was the nice timing of the arrival of a new Secretary of Health and Human Services, Otis Bowen.

Otis Bowen had been the Governor of Indiana, he was a very sharp Republican politician, and he was at HHS—people thought—to be a "caretaker" until the end of the president's term. But Dr. Bowen served with distinction and actually served longer than anybody ever had in that position. I went to see Dr. Bowen several days after he arrived and told him that if his executive secretariat cleared my report on AIDS, it might come through that process looking like a Surgeon General's report on smoking. I made the brash request that I report only to him and that, when he approved of what I would write, we would jointly carry it to the president. He agreed.

My work in preparing the report amounted to walking a tightrope because I needed to be in touch with all of the national groups that were equally concerned, rightfully, about AIDS. I wanted to make sure that they knew what I was doing. I wanted to be sure that when we published the report they could not say that they had been kept in the dark or were blindsided in any way. But what was equally important was that I needed all the help I could get and I did value their input and advice. At the same time, I had to be sure that the report was independent, that it was objective, and that it would be my report and not theirs. To do that I had to distance myself from those same groups that had provided me such encouragement and information.

A few of the meetings that I had were especially helpful. The information provided by the National Hemophilia Foundation was absolutely critical. The Foundation's experience with hemophiliacs who had become infected with the virus allowed these tragic cases to be studied very carefully. This was a major contribution to our understanding of the disease. We also learned about the strength of young people who lived their lives with two diseases, as well as the fear of discrimination around every corner.

The hemophilia experience nailed down the evidence that AIDS could not be spread by casual contact. Six hundred families were very carefully studied. These family members, over a two-year period, touched each other, used the same utensils for cooking, kissed each other, and some shared razors, without passing the virus. Even in the 7 percent who shared toothbrushes—and that figure surprised me greatly—there was no transmission of the virus from infected patients to their toothbrush partners.

This was very important information. It meant, when joined with the information from other studies, that most Americans were not at risk for AIDS if they did not engage in high risk behavior with sex or drugs. It also meant that persons with AIDS should not suffer discrimination, and that the strident calls for quarantine or the denial of housing, insurance, employment, and public schooling had to be repressed.

I had the help of two Public Health stalwarts, Michael Samuels and James McTiegh, in preparing the report. In August of 1986 I began to write the first draft of "The AIDS Report." I wrote and I rewrote, usually in my residence on the NIH campus, down in the basement, at a stand-up desk. Only Samuels, McTiegh, and Assistant Surgeon General James Dickson contributed to the effort. After the sixteenth draft of the report, I took it over to Anthony Fauci, who eventually became the chief AIDS researcher at NIH. He read it and made some excellent suggestions. But, other than that, and three women readers that I selected from amongst the wives of Public Health officials, nobody else really had a chance to look at the report.

The official American response to AIDS, as far as the government was concerned, hinged on two Cabinet meetings. Remember this is a report that I wrote, and the only government

person that officially screened it was the Secretary of HHS. The next level was the Cabinet. The first meeting was with that part of the Cabinet that deals with domestic affairs. They, plus a lot of other people in the White House, are called the Domestic Policy Council. The second meeting would eventually take place in May of 1987 and would involve the entire Cabinet and the President himself.

As may be imagined, at each meeting I had to skate rather fast over thin ice to get by the political appointees who placed conservative ideology far above saving human lives. Knowing the way that the Domestic Policy Council worked, I could see that a certain amount of nitpicking could take place and soon we would either have a report on AIDS written by political advisors to the President, or we would have no report at all. I also knew that these people did not like to spend money and so I decided to take a psychological gamble.

It had been planned to print the report in a brochure that was four by nine inches, on cheap paper, because we planned a first edition of two million copies. But I also ordered 1,000 copies printed on the best quality glossy stock that I could find in the royal blue of the Public Health Service, with a seal in shining silver, and across the top the title, "Surgeon General's Report on Acquired Immune Deficiency Syndrome." I figured that if the Domestic Policy Council were to suggest changing anything in this report they would realize it was going to cost a fortune and they might have second thoughts.

I think my first remark at that Cabinet meeting took those there very much by surprise. I had nothing to lose and much to gain. What I said was:

> From what I read in the newspapers, I have come to the conclusion that this room has a lot of leaks in it. I would be very unhappy if this report were to reach the press before I released it. Therefore I am handing out numbered copies of this report and I hope you will not be offended if I collect them at the door when you leave.

I did not receive any comments, but many eyebrows did go up. I reviewed the report for them, page-by-page, but in a rather superficial manner, and there was very little discussion. White House gossip informed me later on that the gentlemen at the meeting did not want to discuss condoms with ladies present. So I knew that what I had said had not been absorbed in any depth by anyone.

But at long last, on October 22, I called a press conference and released the AIDS report. Of all the statements that I made, only two words seemed to be remembered: "Sex education." The next few days were spent fending off the press, and answering questions about my ideas on when sex education should begin. Many of the larger issues in that AIDS report were eclipsed temporarily by this distraction.

In the meantime, having failed to come to grips with the AIDS report when they first read it, the political meddlers in the White House tried to bottle up the whole effort. In a very unusual move, two members of the Domestic Policy Council came across town to the Humphrey Building to interview me. Usually, when the White House calls, it is a command appearance at their place, and you go. What they came to ask me was if I did not think it was time to update the report.

The report was only two weeks old. AIDS was moving along fast, but not that fast. The report did not need any updating. In fact, that report does not need any updating today. Of course, what the members of the Domestic Policy Council wanted me to do was to take out the word "condom," and this I refused to do. Meanwhile the presses were running, the mail trucks were rolling, and the report went out. At last, the people of the country did have

something in hand that could tell them what was myth and what was fact about the AIDS epidemic, and they could read it in plain English.

But people wanted to hear more, and I found myself deluged by requests from all over the country to speak at various meetings, conventions, and even to combined sessions of state legislatures, which I did in California, Texas, and Minnesota. America finally was getting mobilized for the first time against this epidemic. France and Australia requested permission to publish parts of the report. And a new and surprising band of opponents suddenly materialized against me. I found myself praised by my formal liberal adversaries and condemned by my former conservative allies. Everybody, or at least those who did not know me, said that I had changed. Conservatives said that I had changed and they were angry; liberals said that I had changed and they were pleased. But I had not changed at all. All the fuss surprised me somewhat. I just did what I had always done as a doctor. My whole career had been dedicated to prolonging lives, especially the lives of people who were weak and powerless—the disenfranchised—people who needed an advocate, newborns who needed surgery, handicapped children, unborn children, baby Does, and people with AIDS. They were all the same to me.

Some of my new opponents were more annoying than alarming, like Phyllis Schlafly. Why anybody paid attention to this woman is one of the mysteries of the 1980s. Maybe no one really did, but she certainly buzzed around me like an angry hornet. Phyllis Schlafly would rather have seen promiscuous young people contract and transmit AIDS than expose her own children to the knowledge that there were such things as condoms.

I did not like having to talk about condoms, I must admit. It was very difficult for an old-timer, about to celebrate his seventieth birthday and fiftieth wedding anniversary, to be called "The Condom King." Sometimes talk about condoms in America in the wake of the AIDS report reminded me of seventh grade children who finally found out that they could go behind the barn and say naughty things. But I have to reiterate what I have said so many times. I never, in public, on television, on radio, in lectures, talked about condoms as a preventive measure against AIDS without first stressing abstinence for young people and mutually faithful monogamy for older people. But the press never reported anything I said about abstinence or monogamy, only that I was for condoms.

If the general public seemed to be making substantial progress in learning about AIDS, the White House still was not on board. I quickly saw—or it was not quickly; I came to this decision rather slowly—that the Reagan White House, including the President himself, reasoned usually in an anecdotal fashion, instead of examining the evidence and acting upon those conclusions. In one of many examples, at another meeting of the Working Group of the Domestic Policy Council, one member, a nurse no less, said that there were many people in the country who believed that AIDS was transmitted by cats, by mosquitoes, by door knobs, by typewriter keyboards, and toilet seats. She said, "Who was to know? Maybe they are right and the government is wrong?"

These discussions about AIDS with a variety of high level government officials depressed me about the lack of intelligence among some people in high places. The major problem was that the President was reluctant to go out front offering the leadership that only he could provide. At least a dozen times I pleaded with my critics in the White House to let me have a meeting with President Reagan so that he could hear from me my concerns about America and the AIDS epidemic, and what his role in it should be. For months I had been trying to cover the rather embarrassing silence of the Oval Office on the scourge of AIDS. I kept telling myself that the President would soon speak out. Finally he did, in April 1987. The occasion was interesting because it was back in my home town of Philadelphia.

President Reagan went there to celebrate with a speech the 250th anniversary of the oldest coterie of medical people in this country, the College of Physicians of Philadelphia. The day before he went, I received a call from one of his assistants, not from a speechwriter, who asked me, "Do you think the President ought to mention AIDS?" I said I thought that was the purpose of the occasion. Reagan did mention AIDS, for the first time in public in Philadelphia, touching upon the epidemic briefly and superficially in his speech.

That afternoon, when he went to the Philadelphia Airport to get on Air Force One to go home, he was crowded by reporters who kept asking him question after question to which he replied nothing at all until he got to the top step, and was just about to enter Air Force One. Then he turned and said, "Just say no." That night Tom Brokaw reported on the NBC evening news that the President had never read *The Surgeon General's Report on AIDS.*

By the spring of 1987, it had become obvious that one issue would shape official policy on AIDS in the United States, and that issue was testing for the antibodies to the virus. At first the suggestion was to test many people. With a killer disease on the loose, it seemed a good idea to test everybody and see who had it. But a little more thought on the issue fortunately revealed the shortcomings of that rather simplistic solution.

First, what was to be done with those who tested positive? Of course, I had already heard from those congressmen and others who wanted either to kill those infected or to put them in concentration camps. There was that little issue of the Constitution which did not allow the rounding up of people just because they were sick. AIDS became an issue, therefore, not only of health, but also of civil rights.

Widespread AIDS testing could result only in widespread discrimination against people who tested positive. Already the American people, at least those Americans who thought with justice and compassion, were horrified by stories such as that of Ryan White, the schoolboy who was driven by fear and hatred from his school and town in Indiana. Then there was the Ray family in Florida that had three young hemophiliac boys infected with HIV through no decision that they ever made. They suffered not only humiliating discrimination, but they saw their house burned down by arsonists, presumably fearful and hating neighbors.

Above all, mandatory AIDS testing would drive underground and away from counseling the very AIDS-infected people who needed help the most. Those, indeed, who needed help not only with their own health, but who needed help in reforming their behavior so that they would not infect others. Driven underground, these people would only continue to spread the disease. Health officials, unlike some laymen, were adamant about the importance of AIDS testing but knew it would serve its purpose only if the tests were voluntary and absolutely confidential.

Amidst this controversy about testing, at last, there would be a Cabinet meeting devoted primarily to AIDS. As far as I know, it was probably the only Cabinet meeting in the Reagan administration at which AIDS got the attention it deserved. At issue was whether President Reagan would follow the advice given to him by the Public Health Service and the Secretary of Health and Human Services, or whether he would choose the plan of mandatory and widespread testing advocated by some of the political hacks in the White House.

At the Cabinet meeting I was sitting in the second row and rather unobtrusively, I thought, I pushed my chair back about six inches so that I was sitting with Robert Windom, Assistant Secretary of Health, on one side and James Mason, the director of the CDC, on the other, but nobody in that room could see my face except the President, who was sitting right across the table. Whenever the President had a question that I wanted to answer, or whenever I wanted to reinforce or rebut something that I had just heard, I raised my right index finger to my nose and sort of nodded at the President. He acknowledged me on every

occasion without anyone knowing that I had asked to speak because every time he acknowledged me, he said something like, "I would like to hear from Dr. Koop on that," or "Dr. Koop, would you care to comment on that?" The system worked eight times. There were no misses. I like to think that it steered the President toward his decision to espouse the precepts of the Public Health Service on AIDS. "Testing," he said several days later, "would remain voluntary and would remain confidential."

I was so pleased with this outcome that a couple of nights later when I attended an AMFAR function in a huge hot tent on the Potomac River, I barely noticed the pickets outside who were shouting obscenities as I entered and carrying placards that said, "Quarantine Manhattan and Burn Koop," and other equally encouraging messages.

Our position against mandatory pre-marital testing was eventually vindicated by the states that adopted it, Illinois and Louisiana, because they later repealed their testing laws. There is one anecdote that I do not think many know about, and that is that there was another state that was planning to have mandatory pre-marital testing. That was the State of New Hampshire, and John Sununu was the Governor. One day I received a telephone call from a Bob Wilson. I have met I do not know how many Bob Wilsons in my life. I finally straightened out on the phone that the caller was the Bob Wilson who had been my intern when I was the Chief Surgical Resident at the Hospital of the University of Pennsylvania. He was now practicing pediatrics in Concord, New Hampshire. He said, "I do not understand your position on pre-marital testing for AIDS. Would you explain it to me?" I did not know that, in addition to being a pediatrician, Bob Wilson was also a state legislator, nor did I know that John Sununu had a bill before that legislature for mandatory pre-marital testing. When I finished talking to Bob Wilson, he went across the street, rose on the floor of the New Hampshire State House, and said, "I have just gotten off the telephone with the Surgeon General. These are the facts about pre-marital testing. I move we vote and defeat the bill." And they did.

Two weeks later I went to New Hampshire for my fiftieth reunion at Dartmouth. By that time I had assumed a kind of quasi-celebrity status, and so the college administration was showing me off to anybody they could, including the luncheon speaker, who was John Sununu. As I was being brought up for the introduction, I could see the fire in Sununu's eye. Before he could say anything to me, I said, "Before you say a word, sir, let me explain the embarrassment that you endured on the floor of the legislature in reference to pre-marital testing." I explained about the call from Bob Wilson and then I said, "However, sir, the day will come when you will be extraordinarily grateful, because that was really terrible legislation."

The AIDS report had done its job. I think it had made accurate information available to the American people. But we knew from the start that making the information generally available did not mean that the people would receive it individually. We in the Public Health Service had discussed several times the idea of mailing a copy of that report to everybody on the Internal Revenue Service mailing list, which is the largest such list anywhere in this country. Eventually it was taken out of our hands because Congress, feeling somewhat embarrassed, ordered that such a mailing be undertaken. They did it in several ways. One, they appropriated the money, which was essential. But then they rather insulted Health and Human Services by saying that the document need not be cleared at any level higher than the Director of the Centers for Disease Control. That director actually bucked it up to the Secretary of HHS which was still Otis Bowen. The brochure was all set to go, and it was going to be the largest mailing in American history, 107 million copies. Then the question came up, who would sign the letter which was part of the mailer? I can say that more people came out of the woodwork wanting to sign that letter than I thought were working at HHS.

Otis Bowen, again, handled the situation with his usual aplomb. He had the advertising agency do some studies with focus groups and then he called together all the would-be signers and said, "When you ask for a consultation and you do not take the advice of the consultant, you are a darned fool. We asked for consultation. We had some focus groups. And the focus groups tell us that they would like to see that letter signed by the Surgeon General, so Chick, you sign the letter." So that is how the brochure finally went out.

We made only one small mistake in that brochure. It had nothing to do with the message; it only was in the format. It was a part of the brochure that explained that it was not possible to tell what a patient with AIDS looked like and the headline said, "This is What AIDS Patients Look Like." And we inadvertently put Anthony Fauci's picture right next to the headline.

After this AIDS fully occupied my time. Bob Windom said that there was AIDS, AIDS, and AIDS. I would just like to offer a couple of items out of a diary I kept at the time. The diary has rather a staccato-like style, but it shows the kind of things that I spent time on and the kind of opportunities that provided themselves. This is an excerpt that is about a page long:

> Spent a week in West and East Berlin on AIDS. Met with [Benjamin] Hooks and NAACP on AIDS, then spoke briefly with Jesse Jackson. Made a public service announcement on AIDS with Ed[ward] Koch, Mayor of New York. Discussed the issue of providing clean needles to drug addicts but came up against the claim that often drug addicts want to share used needles as part of their camaraderie. Met with representatives of the AMA [American Medical Association] and the pharmaceutical industry and bounced off them my idea for incentive testing; that is, get tested and be listed by number to take priority advantage should the day come when a better drug than AZT was available. Spoke to the Evangelical Christian Publishers about hating the sin but loving the sinner. Spoke to 900 recruits and 650 instruction officers at the Army's Fort Leonard Wood in preparing a video to be seen by all recruits in the future to the United States Army. Learned that the Army personnel who speak to AIDS counselors at social functions are assumed to be seropositive, thus putting AIDS counselors in social isolation. Spoke in Cincinnati to the National Council of Juvenile and Family Court Judges and was concerned that the questions asked revealed how little was understood about AIDS even by these learned people. Discussed with teenagers how, when you have sex with someone, as far as disease was concerned, you're having sex with everyone they've had sex with and everyone those people had sex with. Taped the HBO show on "Everything You've Ever Wanted to Know About AIDS But Were Afraid to Ask." Met with labor groups about AIDS. Health attendants contact with splashed blood has become an issue. Went to NIH with President Reagan and new members of the AIDS Commission where the President and I, alone in an anteroom for security reasons, discussed AIDS briefly. That's the longest conversation I ever had with him, but long enough to have a good conversation. Participated in a bipartisan briefing on AIDS run by Senator [Edward] Kennedy. Met with Bill Smith from the Academy of Health Education who has $118 million dollars from WHO to teach AIDS in the Third World. Visited with Margaret Hagarty and

AIDS workers in Harlem Hospital. Visited clinics in Greenwich Village. Met with gay and lesbian groups.

And on and on it went. AIDS indeed consumed my life for those next two years.

In conclusion, the first phase of America and AIDS, that is from the first case in 1981 until the AIDS report of 1986, was marked by mystery and by fear, by much suspicion and judgment and a lot of nonsense about the unknown. The second phase, which is the time when I made my contribution, I think, saw health officials overcome considerable opposition, some misguided, some mean-spirited, to bring at last the facts of AIDS before the American people. In the AIDS report, the AIDS mailer, and the hundreds, and even thousands, of articles and television programs about AIDS, this was accomplished.

I have often noted, and will do so again, that the press did a remarkable and commendable job of communicating the issues of AIDS. The American people learned that, except for babies who got AIDS from their mothers, and except for innocent sexual partners of AIDS carriers who took no precautions, in order to get AIDS they had to engage in risky behavior. Fortunately, that kind of behavior many Americans thought was either illegal, or immoral, or both, in addition to being very risky.

In that second phase of AIDS, Americans sorted through the issues of testing, of discrimination, and of civil rights. In general I think they rejected the bad laws and approved the good ones, assuring people who did not practice high-risk behavior that they were protected from this disease, and also, in general, protecting the civil rights of those who were HIV-positive. But the disease, the epidemic, continued to grow in American society, claiming more and more victims each month.

So we entered the third phase of AIDS in America, and that is the phase we are in now, when society, the health care system, and probably each American will have to come to grips with AIDS because of friends, and perhaps even relatives, who die from this horrible disease.

The CDC and the Investigation of the Epidemiology of AIDS

James W. Curran

In my paper, I will try not to disappoint historians who prefer that the people who were involved in historical events only discuss the facts. I know that historians prefer that facts be *interpreted* by those who have had more experience in doing so, and by those who are far enough removed from events to have the appropriate perspective. People who are involved in making history may be allowed their own judgments about events, but the events are best looked at from a distance.

The problem with the particular history of AIDS is that the events are too close, even for those of us who are trying to develop perspective, because AIDS is still a new epidemic in the history of the world. I will not therefore discuss the facts of the AIDS epidemic very much; I will mostly discuss attitudes and concentrate on the present, offering only a few reflections on the past.

I began working on AIDS about two weeks before the report on the first five cases in the world was published, and at that time I was detailed by the Centers for Disease Control (CDC) to work on the problem for a period of three months. That is now over twelve and a half years ago.

The epidemic is difficult for me to discuss historically because I have so many emotions about the history of HIV and AIDS. On the one hand, the last twelve and a half years, have been characterized for me by a richness of experience, getting to know the Karen Heins, the June Osborns, and many other people, watching them work, and apply their lives, both private and professional, to working on AIDS; getting to know the political appointees who stand out in the AIDS prevention effort, such as Dr. C. Everett Koop, the former Surgeon General of the United States, and Admiral James Watkins, chairman of the 1987 Presidential Commission on the Human Immunodeficiency Virus Epidemic. They are the ones who went against the tide and demonstrated commitment and objectivity when it was not expected. One of the reasons why Dr. Koop was such an excellent leader was that he did not do what was expected of him by the public health community. I can remember walking down the street in San Francisco, worrying about the forthcoming *Surgeon General's Report on AIDS*, and thinking, "What will Dr. Koop do?" When I finally read the report, I thought, "My God, he did it! He is writing as an objective doctor. He is not what the newspapers say about him." Dr. Koop was undoubtedly misunderstood. But his actions demonstrated leadership.

Moreover, Dr. Koop persisted. He acted in the same way with regard to the mental and physical aspects of abortion, and several other issues; when he was called upon to be an objective scientist, he laid it on the line. Admiral Watkins acted in a similar manner. He applied himself with diligence, worked hard, came to understand the problem of AIDS, and then wrote a report for the Presidential Commission that was objective.

In the course of the epidemic, I got to know Anthony Fauci, Robert Gallo, Samuel Broder, Antonia Novello, and many others inside government who were committed to HIV/AIDS research, care, and prevention. I saw the commitment of public health professionals over a period of a decade when it could be easy, exciting, or difficult to work on AIDS. I saw some of the same people apply their commitment and their ingenuity whether they were praised, ignored, or condemned and vilified, often for being the same people and doing the same job. I also came to know many people in the larger community, including many clinicians and many community workers. I learned that nongovernmental organizations can vitalize efforts for disease control. Those were the good experiences that came about for me from the AIDS epidemic.

The bad things that resulted from it relate to an awful sense of unfinished business. That is one of the reasons that I am hesitant to discuss AIDS from a historical perspective. The past is nothing compared to the present or the future when it comes to HIV and AIDS. Therefore, I will first make three points, then elaborate on them, and, finally, describe my philosophy about the future of AIDS research, care, and prevention.

My first point is that everyone must think of the HIV/AIDS epidemic as just beginning. I cannot emphasize this enough. It has only been a couple of decades since the epidemic began, and two decades is nothing in the history of a disease. The first AIDS cases in the entire world were reported in 1981. The existence of HIV-positive sera specimens stored since the 1950s and the issue of whether monkeys had related viruses can be discussed, and many other questions that are relatively unimportant in terms of trends in human suffering. But compared with the spread of the virus throughout the world in the last twelve years, the previous occurrence of HIV infection is unimportant. Even the spread of the virus in the last twelve years is nothing compared with what will happen in the next two or three decades. Those of us who live long enough will see hundreds of millions of people become infected with HIV, and hundreds of millions of people die of this disease. That is much more important than everything that has preceded it. This is why I say that history is just beginning when it comes to HIV/AIDS.

My second point is that I like to refer to eras in the AIDS epidemic. I would divide the two decades since the first reported cases into three eras: the first five years, the second five years, and then the rest of the history, or up to the present time. The first era I call the "Era of Discovery"; the second, the "Era of Growth"; the third, "The Long Haul," which is right now, I subtitle the "Era of Crisis and Opportunity."

My third point relates to leadership—we need to find more C. Everett Koops, more Admiral Watkinses, and more June Osborns, and keep them instead of discrediting them. Our leaders should be nurtured and not eaten alive. We need more people who do what leadership requires, and that is to rise above the fray and develop consensus on important issues.

With HIV and AIDS it is extremely tempting to be reductionist. We always have to deal with that, of course, in the scientific approach, even to issues that are not very important. In reflecting about the last few years, one of the problems we have had with leadership is our tendency to be concerned about issues that are more important symbolically than in their quantitative impact. For example, the preoccupation with health-care-worker-to-patient transmission (a preoccupation that I think will continue for the next several years because of liability and misconduct issues), is not central to the spread of AIDS. But issues such as this have become dominating AIDS issues to which we all react. They are not the real issues that leaders must identify and place on the public agenda as crucial.

Leaders have to identify the important issues and keep hammering them home, even if the issues are the same ones as they were five years ago; and leaders have to persuade other

people to follow them. Perhaps the first thing a would-be leader should do is to find out who his or her followers are likely to be; then determine if the available science and the followers' perspectives are compatible with being the leader of such a group; and finally decide whether he or she has what it takes to be a leader.

The way we approach HIV and AIDS can be a paradigm for tackling many of our future public health problems in terms of involving communities in helping to change community norms and individual behaviors. Delivering effective prevention programs for disease demands strong community support. We already know, for example, that even if safe and effective vaccines are available, people do not necessarily get vaccinated early enough. Science is not all that is needed for effective public health programs; at least not laboratory and biomedical science. There has to be more behavioral science applied, and more involvement of the people in the affected communities themselves.

Finally, the definition of leadership that I like the best is one of "constantly redefining the unacceptable." I think that leaders have to learn what is preventable in terms of a public health problem, keep redefining it to make sure that the definition is fresh, and then make certain that people do not accept it just because they are bored with it.

The first two *Morbidity and Mortality Weekly Report* (*MMWR*) articles relating to AIDS came out in 1981. A handful of infectious disease clinicians and immunologists at the University of California Los Angeles (UCLA), and at Mt. Sinai, Cornell, and other places in New York were identifying *Pneumocystis carinii* pneumonia in young gay men and, in New York City, in a few other poor men who at the time may or may not have been drug users. From 1969 through the 1970s and into 1980, only one case of *Pneumocystis carinii* pneumonia was diagnosed in a person who was not on immunosuppressive therapy, who did not have underlying cancer, or who had not had a transplant that required treatment with pentamidine isothionate, an investigational drug then only available through the Centers for Disease Control. Then a handful of pentamidine requests started coming in to the CDC, and an administrative assistant named Sandra Ford, who was very ambitious and perceptive, noted, "This is strange." She called her supervisor's attention to the surprising number of requests.

The CDC had assigned an Epidemic Investigation Service (EIS) Officer, Dr. Wayne Shandera, to Los Angeles, California. He worked with a physician, Dr. Michael Gottlieb, an immunologist at UCLA, who had studied two or three of these unusual cases. Dr. Shandera suggested describing the three cases identified at the time and publishing a report in the *MMWR* to warn people about the illness, and perhaps see if more cases might be identified.

By the time Gottlieb and Shandera had written the report, there were five cases. Since I was one of the investigators of the Hepatitis B Vaccination Trials in Gay Men that the CDC was conducting with Merck & Co. and several health departments, and since I was Chief of the Research Branch of the Sexually Transmitted Disease (STD) Division at the CDC at the time, the draft article came through for my review. Later, Harold Jaffe, a colleague at the CDC, and I had a chance to talk to a few of our gay physician friends who were working on the Hepatitis B Vaccination Trials, and we found out that a couple of them had also seen cases like those in Los Angeles.

In addition, the late Dr. Linda Laubenstein, an oncologist at New York University, and Dr. Alvin Friedman-Kien, a dermatologist who had trained at the National Institutes of Health (NIH), had seen a few cases of Kaposi's sarcoma in New York. They, along with Dr. Bijan Safai and several others in New York City, reported these cases to the CDC. It turned out that a large portion of the New York patients also had opportunistic infections and underlying immunodeficiency.

It was the persistence of people such as Michael Gottlieb, Henry Masur (in New York City at the time), Alvin Friedman-Kien, and other scientists like them, that got the NIH involved by demanding, first of all, that the National Cancer Institute (NCI) do something about this new disorder. The NCI actually had a meeting which was eventually cosponsored by the National Institute of Allergy and Infectious Diseases (NIAID) and the CDC in September of 1981 to bring a group of people together to talk about the problem.

My first few trips to the NIH came at NIH expense because all of us, at that time, were starving for travel funds. I do not know whether many people now remember the imposed personnel reductions, all of the Public Health Service hospitals closing, and the proposed budget cuts in the federal agencies in 1981. But the NCI found the travel money to have me come to Bethesda, stand at a podium, and talk to their various boards so that they would agree to put $200,000 or $300,000 into the hands of some of these scientists studying Kaposi's sarcoma. In 1981, the boards were not completely convinced that the Kaposi's sarcoma was related to the immunodeficiency, but they were listening to their scientists and had the insight to see that this was something new.

It was around 1982 that Dr. Shandera's successor in investigating the cases in Los Angeles, Dr. David Auerbach, was approached by a man who showed him a picture album and who said that he had been at a dinner party in Los Angeles to benefit the gay community. Several hundred people had been at the dinner party; ten people were at his table, none of whom he had met before, and four of them had since died of this new disease. As there were only thirteen cases in Southern California at the time, the man thought that this was strange. Dr. Auerbach agreed with him. From that encounter came investigations by Dr. Auerbach and Dr. William Darrow, a sociologist at the CDC, that linked the cases we *referred* to as "Out-of-California Kaposi's Sarcoma" by sexual contact with a person called "Patient Zero," with, first of all, four other cases. Ultimately, through interviews done in person with 90 of the first 215 gay men with AIDS in the United States, Dr. Darrow was

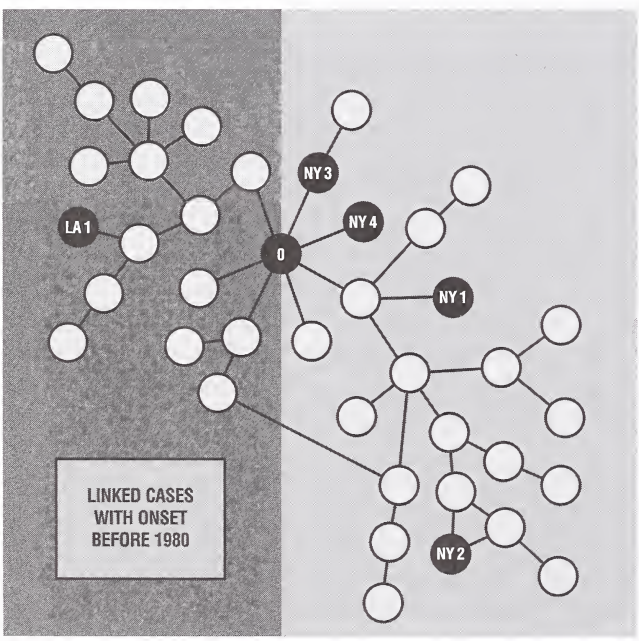


Figure 1.
AIDS cases with onset linked by sexual contact.

AIDS case

AIDS death

0 *Patient zero*

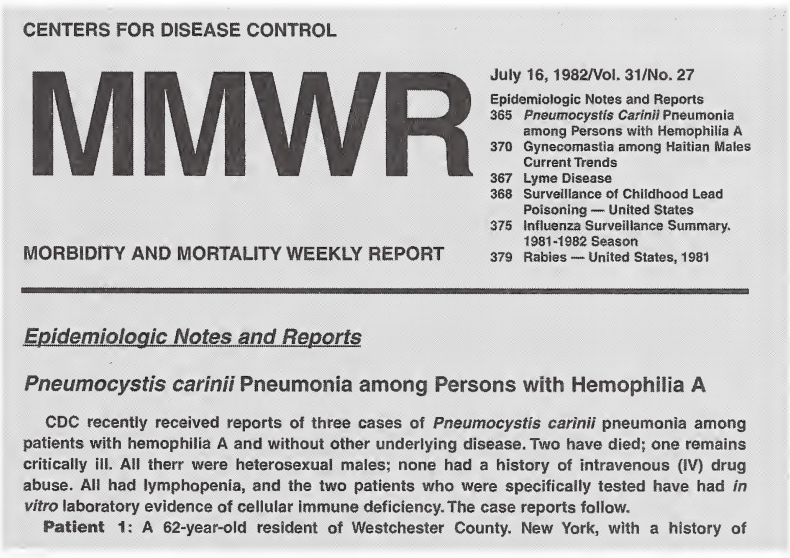
Source: Centers for Disease Control and Prevention.

able to link 42 of those 90 cases to each other through sexual contact (Figure 1).

This cluster convinced us that this syndrome was most likely transmitted through sexual contact. Many of the people investigated were the only case of AIDS in their state, and yet, somehow, they had met one of these other patients before most of them had any symptoms. But they would subsequently be developing symptoms. Although, by 1982, this evidence suggested sexual contact as a means of acquiring the syndrome, most scientists were not convinced.

The most important cases, in terms of changing scientists' views on what was happening, were the three cases reported in July 1982 among persons with hemophilia A. The first case was reported after the man, who was elderly, had died. The second two cases were intensively investigated by Dr. Dale Lawrence, who is now with the National Institute of Allergy and Infectious Diseases. Dr. Lawrence is a very persistent man. He went and practically lived with the families of the two hemophiliacs for about two weeks. He went over every possible record they had on treatment and clotting factors, talked to everybody in the community, and was absolutely convinced that these two men, from two states which had not yet had many cases, had the same disease. They had *Pneumocystis* pneumonia as well as severe unexplained immunosuppression, and they had not had homosexual contact or shared needles with any other person.

The third hemophilia case was confirmed three days before a July 1982 meeting on the syndrome that was held at New York University. Dr. William Foege, who was then the Director of the CDC, was giving a five-minute presentation on the infectious etiology hypothesis for AIDS. Six or seven other people were also to speak on other hypotheses about etiology—semen from many different men, nitrites, drug abuse, and homosexuality itself. Dr. Foege spoke first and reported that descriptions of these three new cases in hemophiliacs would be published in the *MMWR* the next day, July 16, and that these cases strongly pointed toward a viral etiology for AIDS because the men had received blood products from many thousands of donors (Figure 2). Each speaker who followed changed his or her talk to a cofac-



CENTERS FOR DISEASE CONTROL

MMWR

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July 16, 1982/Vol. 31/No. 27

Epidemiologic Notes and Reports

365 *Pneumocystis Carinii* Pneumonia among Persons with Hemophilia A
370 Gynecomastia among Haitian Males Current Trends
367 Lyme Disease
368 Surveillance of Childhood Lead Poisoning — United States
375 Influenza Surveillance Summary. 1981-1982 Season
379 Rabies — United States, 1981

Epidemiologic Notes and Reports

***Pneumocystis carinii* Pneumonia among Persons with Hemophilia A**

CDC recently received reports of three cases of *Pneumocystis carinii* pneumonia among patients with hemophilia A and without other underlying disease. Two have died; one remains critically ill. All therr were heterosexual males; none had a history of intravenous (IV) drug abuse. All had lymphopenia, and the two patients who were specifically tested have had *in vitro* laboratory evidence of cellular immune deficiency. The case reports follow.

Patient 1: A 62-year-old resident of Westchester County. New York, with a history of

Figure 2. This July 1982 article reported cases of AIDS in three hemophiliacs. Because each had received blood products manufactured from thousands of donors, their cases of AIDS pointed strongly toward a virus as the cause of AIDS.

Source: Centers for Disease Control and Prevention.

tor talk spontaneously, because Dr. Foege's evidence was so convincing to everybody working in the field. The three hemophiliac cases in July 1982 were very important; in the next nine months scientists and the public became convinced that something had to be done about protecting the blood supply, that this syndrome was very likely caused by a virus, and that it was being transmitted from person to person.

The first cases of heterosexual transmission of AIDS were reported from New York City by Drs. Gerry Friedland, Neil Steigbegel, and others, investigators at Montefiore Hospital, on 7 January 1983, in the *MMWR*. These cases occurred among women who were female sex partners of men with AIDS. But most researchers did not believe in heterosexual transmission of AIDS, even though it was first reported from New York City, until it became epidemic in Africa. Then, in an overreaction, some experts and reporters assumed that the epidemic in heterosexuals would be as large an epidemic as that among gay men in the United States. Instead, it has been a rather predictable, slowly growing heterosexual epidemic with the roots in poverty and injection drug use that had first been noted in New York and New Jersey.

Infants with AIDS were reported in 1983, including the first baby with transfusion-associated AIDS. AIDS, by then, had also been reported among Haitians who had migrated to the United States, and among persons from central Africa, principally from Zaire, who had been diagnosed and treated in Belgium. Several investigators, again primarily from New York and California, had reported that a number of unexplained illnesses were being seen, including lymphadenopathy and weight loss, in the same groups of people—that is, persons with hemophilia and gay men that had AIDS. For that reason, several of us described the known AIDS cases as "the tip of the iceberg." I think the CDC distributed more illustrations depicting the "iceberg" than we did the *Surgeon General's Report on AIDS* (Figure 3). We all knew that the problem was bigger than it seemed, and we wanted to emphasize that it involved many more people than just those few cases that had been reported. We knew this in mid-1982.

During the first two years I was "detailed" to work on the epidemic, I received some-

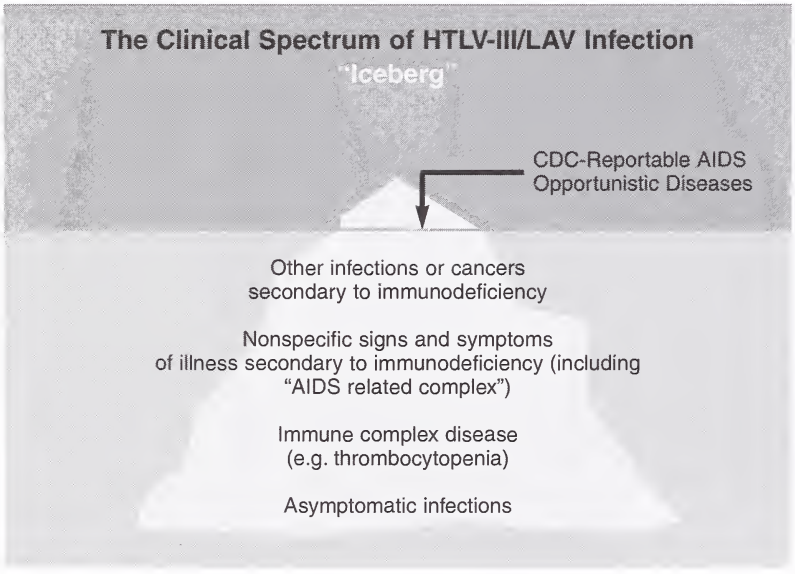


Figure 3. AIDS "iceberg" image, showing that reported cases represented only a tiny portion of those infected with the AIDS virus.

Source: Centers for Disease Control and Prevention.

thing like 75,000 letters proposing theories about the cause of AIDS. But no one had proof of a cause.

However, in March 1983, nine months after the first three cases in hemophilia patients had been reported, even though the virus had not been discovered, the Public Health Service, the NIH, the Food and Drug Administration, and the CDC, published consensus recommendations on the prevention of AIDS. The syndrome was named twenty-two months after the first five cases were reported. The prevention recommendations were recommendations related to sexual contact, blood donation, and injection drug use, and are essentially similar to the ones that we have now ten and a half years later. Virtually every other organization in America, and throughout the world, made recommendations that were quite similar to these 1983 ones, and I think this was a great tribute to Public Health Service leadership.

At that time there were 1,000 cases of AIDS in the United States, and many places had 20 cases or more. Compared to now, the country was still largely barren of AIDS and few cared about the disease. One thousand cases. That is now about three- to seven-days worth in terms of the number of reports of AIDS cases that the CDC received in 1993.

The virus was discovered and causality proven in papers by Drs. Françoise Barré-Sinoussi and Luc Montagnier in 1983, and by Dr. Robert Gallo and his colleagues in early 1984. By then, it was quite clear that the cause of AIDS had been discovered, and that an antibody test would be available to protect the blood supply. By May 1985, two months after the antibody test was licensed and testing had begun in all blood banks in the United States, there were 10,000 cases of AIDS in the United States.

AZT (3'-azido-2, 3'-dideoxythymidine) was already being tested in humans following the work of Dr. Samuel Broder and his colleagues at the National Cancer Institute and of Burroughs-Wellcome, Inc.; shortly thereafter, in 1986, AZT was licensed. All these developments occurred in the first five years of the epidemic, the "Era of Discovery."

The beginning of the "Era of Growth" began more or less in 1986 when Dr. Walter Dowdle was the Acting AIDS Coordinator in the PHS. He and Dr. Ian McDonald, then the Acting Assistant Secretary for Health, convened a meeting at Coolfont Conference Center in West Virginia. At this meeting, PHS leaders, a few outside experts, and one reporter discussed what the future held for AIDS and what the PHS should do about it. The CDC's Dr. Meade Morgan projected that from 1986, when 16,000 cases had been reported, through 1991, 270,000 cases would be reported. The importance of this projection was that it made people think ahead from the "Era of Discovery" to the "Era of Growth."

By 1986, we knew the modes of transmission and the etiology of AIDS, a blood test was licensed, and AZT was licensed. In practical terms, we knew much of what we know now. I am not claiming that science has not progressed greatly since then, but in practical terms, we knew a lot. But Meade Morgan was foretelling the "Era of Growth," an era which meant not only growth of suffering but also growth of demands on those providing service.

What characterized the end of the "Era of Discovery" was that the horizons were uncertain; the transition period was a period of fear, partly because of the ominous PHS projections regarding the future course of the AIDS epidemic. How many people would get infected and how many would die in the long run was uncertain. The phrase "AIDS is different" was coined. Finally, there was a widespread awareness that a "different" response was needed. The sense of urgency meant priority for AIDS. There was "AIDS resentment complex" from the rest of the biomedical science community and the other communities that were saying, "AIDS is now getting too much attention."

The transition period had fear, concern about Africa, uncertain horizons, and the beginning of international awareness of AIDS. The First International Conference on AIDS, for

which there was no admission charge, was held in Atlanta in 1985. Fewer than 2,000 people showed up, but they included many prominent NIH scientists. Secretary of Health and Human Services Margaret Heckler made the opening remarks. AIDS was different.

The "Era of Growth," from 1986 to 1991, was characterized, not only by fear, but also by optimism. From 1986 to 1990, so much more was being done. The press was paying attention to AIDS. Rock Hudson had announced that he had AIDS. Ryan White, a hemophiliac, got AIDS, and his struggle with school discrimination and his illness was widely followed. The blood test was saving people through a safer blood supply. Science promised to produce a vaccine shortly. The rapid discovery of AZT made scientists think, "We will be able to do much better soon, and we will be able to make this a manageable disease like diabetes." Huge growth occurred in Government research budgets for AIDS, and eventually in prevention and care budgets, and the period was characterized by a growth in the number of investigators working on AIDS.

It was hoped that soon, through application of the tools of biotechnology to HIV, the problem would be solved. Even dying AIDS patients were saying, "I hope I can just hold out, because these scientists are going to lick it. We are going to beat this problem." Unfortunately, along with the "Era of Growth" came the "Era of Sickness and Death" for most of the people in the iceberg. Hundreds of thousands of people who were infected and who did not know that they had a viral time bomb in them during the first five years of the epidemic started to get sick and die, and many fell through the cracks in the United States social services and health network during the "Era of Growth."

But there was some justification for optimism during this time period. New attempts were made in working with non-governmental organizations to get researchers to collaborate with people from the community in designing therapy trials, providing services, and preventing infection. Science was now making progress. But, during that same time period, HIV went from being nowhere to being the leading cause of death (in 1992) among men between the ages of 25 and 44 in the United States, and to being the fourth leading cause of death among women aged 25 to 44 in the United States. AIDS/HIV singlehandedly reversed a century-long downward trend in mortality in young men, accounting for about 20 percent of mortality among men in this age group by 1992. In fact, the epidemic, as charted for the World Health Organization by Jonathan Mann, was exploding worldwide.

The press awakened from its sleep in 1983, bolstered by the cases of Ryan White and Rock Hudson. A chart of Lexis/Nexis articles shows something like 120,000 major articles published on AIDS from 1981 to 1993, most in the last ten years. Many media events, however, such as Magic Johnson's announcement that he had AIDS or the announcement of the transmission of AIDS from a dentist to a patient, are not the most important things that happened in relation to HIV and AIDS. Some of them are less important than others. But the topic of AIDS does not go away. The press and the public retain interest. One of the concerns in the current era is that stories about liability and misconduct trials in Germany and trials in France will overshadow interest in the continuing efforts to prevent transmission and to focus on the important deliberations in science.

But then we had another transition period. In the United States and in other industrialized countries, although not in the world at large, the growth of AIDS cases slowed considerably. The horizon became clearer. Whereas in the transition between the "Era of Discovery" and the "Era of Growth," the horizon was uncertain and fear predominated, now people believed that they could "put AIDS in perspective." Those in the biomedical community with AIDS resentment complex could come back and say, "I told you so. It is about time we started paying attention to problems other than AIDS." The transition peri-

od changed popular thinking into "AIDS is not different. Let us put AIDS in perspective." There is now less fear and, hence, more denial. Even young gay men do not think they will get AIDS.

This is a dangerous era. Budgets for AIDS research and prevention have levelled off; people are concerned about many other important health issues. But one thing that has been learned is that HIV is a complicated problem, and that it is associated with other problems such as multi-drug-resistant tuberculosis, poverty, and the deteriorating infrastructure of public health. We also know that in order to prevent HIV infection we have to confront problems related to substance abuse prevention and treatment, tuberculosis prevention and treatment, and care and social services for HIV-infected people, as well as HIV prevention itself. We have to consider issues like homelessness, poverty, prostitution, and substance abuse, if we are going to deal with these kinds of public health problems. Successful HIV prevention programs must invoke a new paradigm for public health. But we have the energy and the leadership to see that paradigm and to employ it.

One of the other concerns in the current era is that the HIV problem is still getting worse and also is changing its face. There is a substantially higher proportion of cases, and a much larger number of women, infants, and minorities are becoming infected and are dying from AIDS. Many persons with HIV were struggling in society, generally, even before they had AIDS. Inherent in the levelling off of resources is the competition for dollars. What do we need more of? Research or care? Care or prevention? Do we need more HIV research or more other research? After all, it has been argued, that many of the most important breakthroughs in the study of HIV can be traced to previous scientific research. Is the levelling off of public concern best termed "complacency" or merely "perspective?"

We are also in an era of skepticism—skepticism about prevention. How can people's behaviors be changed, or how can communities help themselves to change behavior? Certainly there is skepticism about research and care, and skepticism about government and public health. Press reports of the blood scandals and misconduct trials, and all the public debates and uncertainty about public information and condoms fuel this skepticism. Furthermore, AIDS remains a problem which attracts political involvement from all sides. Many of us in the public health field have often felt like the body of a bird being beaten by its right and left wings more or less simultaneously. While political discussion can inform and frame the public debate, often this is not the case with HIV/AIDS.

In the summer of 1985 I gave a talk at the First International Conference on AIDS in Atlanta. At that time, there were about 7,000 cases of AIDS in the United States and the antibody test had just been licensed. I discussed what would be needed if no vaccine or cure had been found by 1990. I acknowledged, first of all, that I was being pessimistic, but said that we should work as if there would not be a vaccine by 1990. It is very sobering to me to think about how limited has been the progress in this area nine years after this talk at the First International AIDS Conference.

My points were as follows:

- We want to reduce the long-term morbidity and mortality due to HIV through education, counseling, testing, and research in vaccines, therapy, and behavior.
- We want to develop and evaluate long-range therapies and apply them to the majority of people with HIV. (The question of whether therapy reduces infectiousness is still being debated, but the evidence from NIH-supported work would suggest that perhaps it may. The resources and the giving of priority to this research are still not there to accomplish this goal.)

In 1985, the problems that I saw as having to be addressed in the future were:

- In the absence of therapy and a vaccine, incidence of AIDS will grow, but at a slower rate.
- The population of AIDS patients will increase in size and age. (It actually has not increased too much in age, but enormously in size.)
- Widespread use of the diagnostic test will identify thousands of infected people. (It was hundreds of thousands by 1990.)
- Policies will be needed for schools, day care centers, prisons, and so on.
- Knowledge of infection status will be recognized as increasingly important in medical management.
- Confidentiality will become even more important for patients and others.
- AIDS and HIV infection will continue to be stigmatizing. (Unfortunately, this is still a major concern. But the Americans with Disabilities Act and several state laws have helped.)
- A larger number of AIDS cases and infections will remain unexplained.
- The modes of transmission will be stable. (There are still only a handful of cases that have not been transmitted by the ways known about in 1985.)
- Finally, the challenge will be anticipation of problems ahead of time to allow planning, consensus development, and avoiding crises.

Problems were anticipated in 1985, yet, as has been found, society still often waits until the problems fester before solutions are developed.

To solve the AIDS problem, a *long-range commitment is needed from the scientific community, the medical and public health communities, individuals at increased risk, and society*. That is, *leadership* is needed.

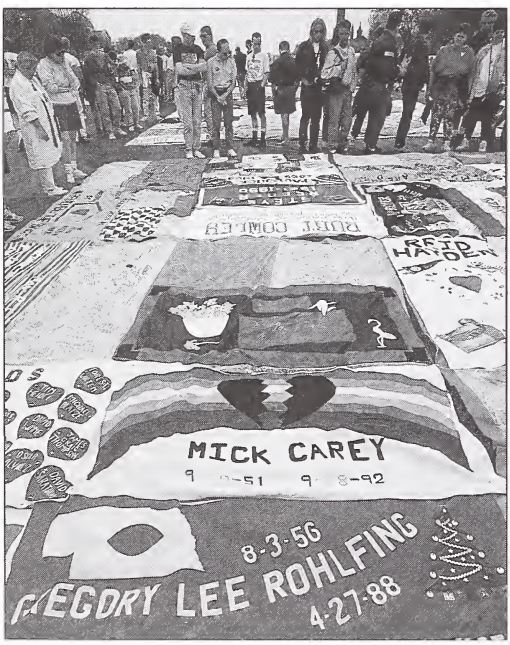


Figure 4.
Quilt sections sponsored by the NAMES Project commemorate individual lives lost to AIDS. Quilt on display in Washington, D.C., 24 April 1993.

Source: ©UNIPHOTO Picture Agency, Bill Auth 1993

I remember patients I have seen who have since died from AIDS. First, a man with Kaposi's sarcoma whom I saw in New York City. . . . A man of Haitian descent from Miami, a patient at the University of Miami in 1982. . . . A Kenyan baby with HIV and AIDS seen by a colleague. . . . A gay man from California who all Americans knew as a movie star. . . . A baby from Romania who acquired HIV through inadequate health care.

Finally, Figure 4 shows the AIDS Quilt (the NAMES Project) on display in Washington, D.C. The scene brings to mind Albert Camus's statement that all people who die of a disease like the plague ought to be brought together in the square of the town so that others have to face them and the magnitude of the problem. That is what the NAMES Project does for AIDS. It takes people who are no longer faces, who even lack demographic features. They are neither men nor women; they are not gay; they are not Americans—they are parts of quilts, just pieces of cloth. By displaying the quilt, we are forced to deal with them, to deal with the failures of public health, and to deal with the challenges to science in the future. We are asked to remain committed, to redefine the unacceptable, to keep trying, never to give up, and to say, "Have we done it yet? Have we succeeded? Has history taught us anything? Or do we just have to watch and wait?"

The NIH and Biomedical Research on AIDS

Victoria A. Harden

During the three decades preceding the identification of acquired immunodeficiency syndrome (AIDS) as a new, deadly infectious and contagious disease, the United States federal government had expanded its activities in the areas of disease control, of medical research, and of regulation of drugs, biologicals, and devices. These efforts were embodied in three agencies of the United States Public Health Service (PHS): the Centers for Disease Control and Prevention (CDC); the National Institutes of Health (NIH); and the Food and Drug Administration (FDA). In this paper, I want to sketch an overview of the response to AIDS of the National Institutes of Health, the federal government's principal agency for support of biomedical research. I will place the NIH response in the context of its role among the PHS family of agencies and of its mission to uncover new knowledge in the biomedical sciences. Having examined how NIH responded to this new disease, I will then describe what unforeseen changes AIDS has brought to the NIH.

Since World War II, federal activity in health has been divided among the several agencies of the U.S. Public Health Service.[1] In 1980, just before AIDS was identified, there were six health agencies under the PHS umbrella. Of these, the FDA was the Service's principal regulatory agency.[2] The CDC, now called the Centers for Disease Control and Prevention but originally known as the Communicable Disease Center, assumed front-line responsibility for identifying the causes of epidemic outbreaks and assisting states with disease control.[3] The NIH was charged with conducting research to discover new knowledge in relation to health.[4] Before World War II, the CDC did not exist, and the NIH performed disease-monitoring functions in addition to the task of uncovering new knowledge. The current division of labor between the CDC and the NIH was crafted in 1946 in the context of the early antibiotic era, when these so-called miracle drugs held promise of utterly vanquishing bacterial diseases.[5] It was solidified in the ensuing decades as vaccines against polio and measles dramatically reduced the incidence of those diseases and a worldwide vaccination program against smallpox apparently eliminated that virus as a human pathogen.[6] By the 1970s, the CDC had demonstrated repeatedly its ability to handle outbreaks of diseases such as typhoid fever and also elucidated the causes of two previously undefined diseases—Legionnaires' disease and toxic shock syndrome.[7]

Initiation of PHS Response

In 1981, as isolated cases of unusual opportunistic infections and Kaposi's sarcoma were gradually perceived as comprising a larger pattern of immunosuppression, the CDC assumed principal responsibility for the Public Health Service's response to AIDS.[8] The CDC leader-

ship did not operate in a vacuum, however. William H. Foege, the CDC director, and the person named to oversee the CDC's AIDS effort, James W. Curran, Chief of the Operational Research Branch, Venereal Disease Control Division, Center for Preventive Services, were knowledgeable about experts in many medical fields who also worked for the PHS, and they called on them whenever it seemed appropriate. For example, in a 30 July 1981 memo to Vincent T. DeVita, Jr., director of the National Cancer Institute (NCI), Foege noted that Curran had already utilized the Kaposi's expertise of several NCI units and requested that DeVita designate a formal contact person for ongoing collaboration.[9] DeVita appointed William D. DeWys, Chief of the Clinical Investigations Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment, as NCI liaison on the new syndrome and further suggested that the NCI and the CDC sponsor a national conference on Kaposi's sarcoma.[10] This meeting was held in September 1981, with the goal of developing "a coordinated strategy regarding the etiology and treatment" of the disease.[11] Participants were unclear, however, about which came first, the wasting syndrome or the cancer and/or opportunistic infections.[12] What did emerge from this conference was the conviction that studies of this "new disease," as AIDS was then being called, should be conducted systematically, under a common protocol, with all patients enrolled in the CDC case-control study.[13]

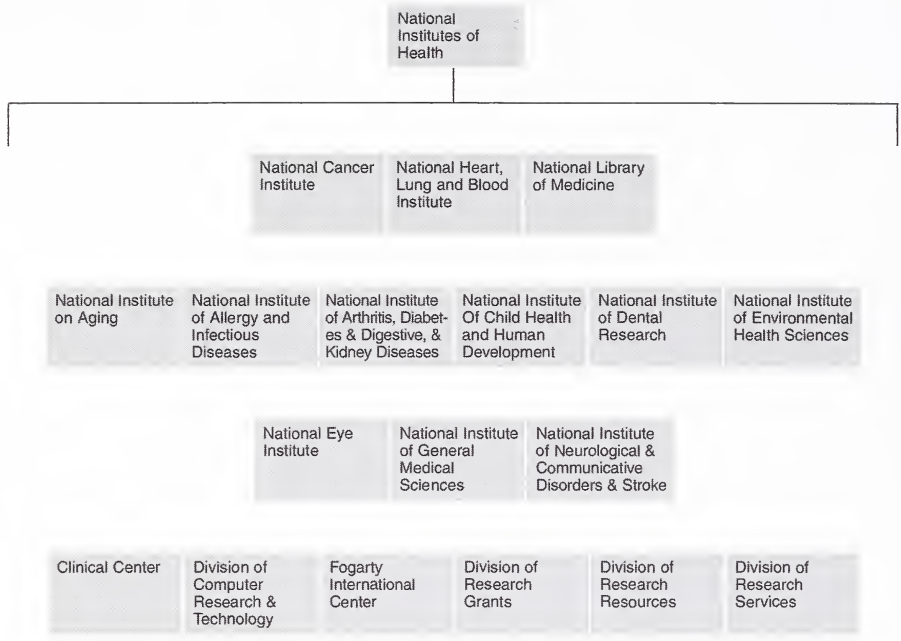
At a 30 June 1982 meeting held at the New York Department of Health, cases of AIDS were reported in intravenous drug abusers, heterosexual hemophiliacs, and Haitians as well as in gay men.[14] This midsummer 1982 meeting marks fairly specifically the point at which epidemiological data persuaded many investigators AIDS was caused by some sort of contagious agent. One NCI attendee returned to recommend that the NIH mount "a most urgent response," including the commitment of monies "in excess of our one million dollars."[15] Within two weeks, an NIH-wide Working Group on the "epidemic of acquired immunosuppression, opportunistic infections, and Kaposi's sarcoma" had been established to disseminate information among interested investigators at the NIH and to maintain liaison with the CDC.[16] At the higher administrative level of the Department of Health and Human Services, findings about AIDS were circulated through regular meetings of PHS agency heads with the Assistant Secretary for Health.[17]

Response of the NIH Extramural Programs

NIH funding for research is divided into the extramural programs of the institutes, centers, and divisions—which make grants, contracts, and other awards to investigators across the United States, and in some foreign countries—and the intramural programs of the various components, most of which are located in laboratories on a campus in Bethesda, Maryland.[18] Funds for grants and contracts in the extramural programs comprise about 89 percent of the NIH budget; funds for the intramural programs, about 11 percent.[19] Figure 1, the 1981 NIH organizational chart, reveals the emphasis on chronic diseases that characterized biomedical research funding in the early 1980s.[20] Only one institute, the National Institute of Allergy and Infectious Diseases (NIAID), was partially dedicated to the study of infectious diseases. The other seventeen semi-autonomous components emphasized cancer, heart disease, aging, arthritis, and other broadly defined, noninfectious problems. Between 1971 and 1975, moreover, Congress had directed the NIH to establish seventeen different targeted programs for research on specific chronic disease problems.[21]

This emphasis on chronic disease research meant that the problem of AIDS did not fit easily into the NIH as it existed in 1981. The underlying medical problem of AIDS patients—the immunodeficiency—was of interest to immunologists, who may have been

Figure 1. The National Institutes of Health, June 1981

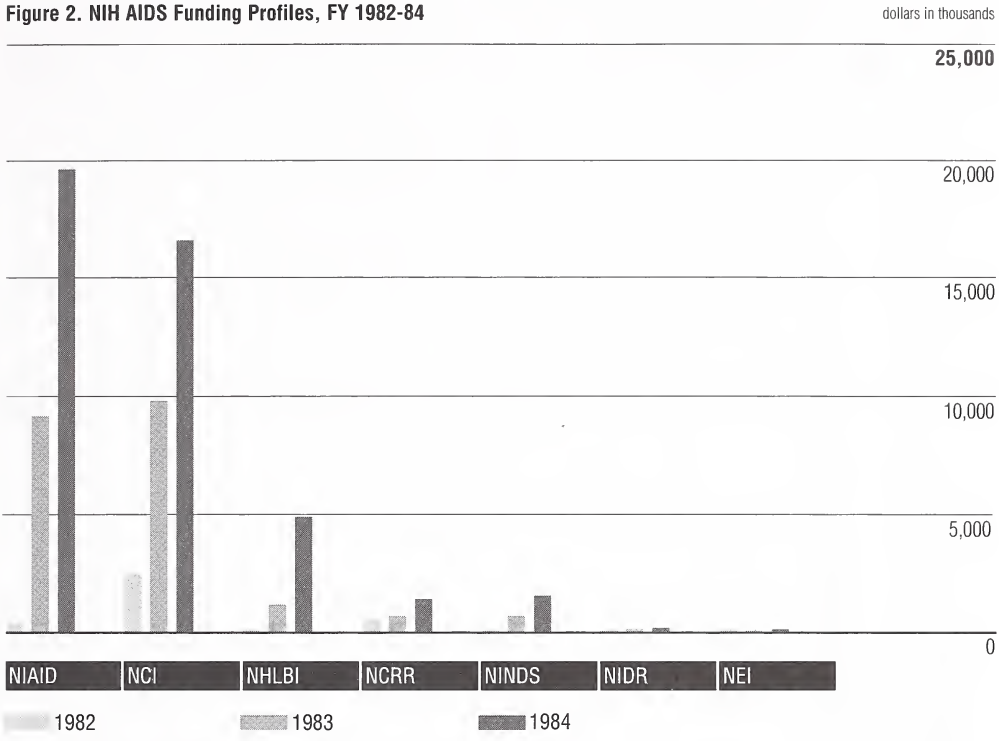


Source: NIH, Office of Program Planning and Evaluation and Division of Research Grants, *Basic Data Relating to the National Institutes of Health, 1981 (Washington, D.C.: NIH Publication No. 81-1261),* p. *i.*

funded by any of several institutes, because in the early 1980s, molecular immunology was such a fruitful field.[22] Research on Kaposi's sarcoma, with which some patients presented, fell into the purview of the National Cancer Institute, and research on opportunistic infections fell under the mission of the NIAID. Before an etiological agent was discovered, therefore, there was some question as to which institute should take the lead in research on AIDS, because of the disease's multi-faceted nature.[23]

Furthermore, the administrative mechanism for distributing grants was also based on the presumption that NIH research would focus on acquisitions of long-term knowledge, not on public health crises such as AIDS. The process went like this: University-based investigators submitted research proposals, which were separated by the NIH according to subject area and referred to groups of nonfederal scientists who were experts in each area—i.e., the peers of the proposers. These review panels gathered three times each year, usually on the NIH campus in Bethesda, to evaluate the proposals for scientific merit. After receiving ratings from the review panels, the applications were reviewed a second time by the advisory councils for each institute, which considered the proposals from the perspective of each institute's mission, placing them in the context of nation-wide policy concerns about diseases and of the need to further research in selected areas. From the time an investigator submitted a proposal until the time funds were received, about eight or nine months elapsed, under normal circumstances.[24] Since 1946, when this program was established, some twenty-two studies of the system had attempted to balance the elitism inherent in any pursuit of

Figure 2. NIH AIDS Funding Profiles, FY 1982-84

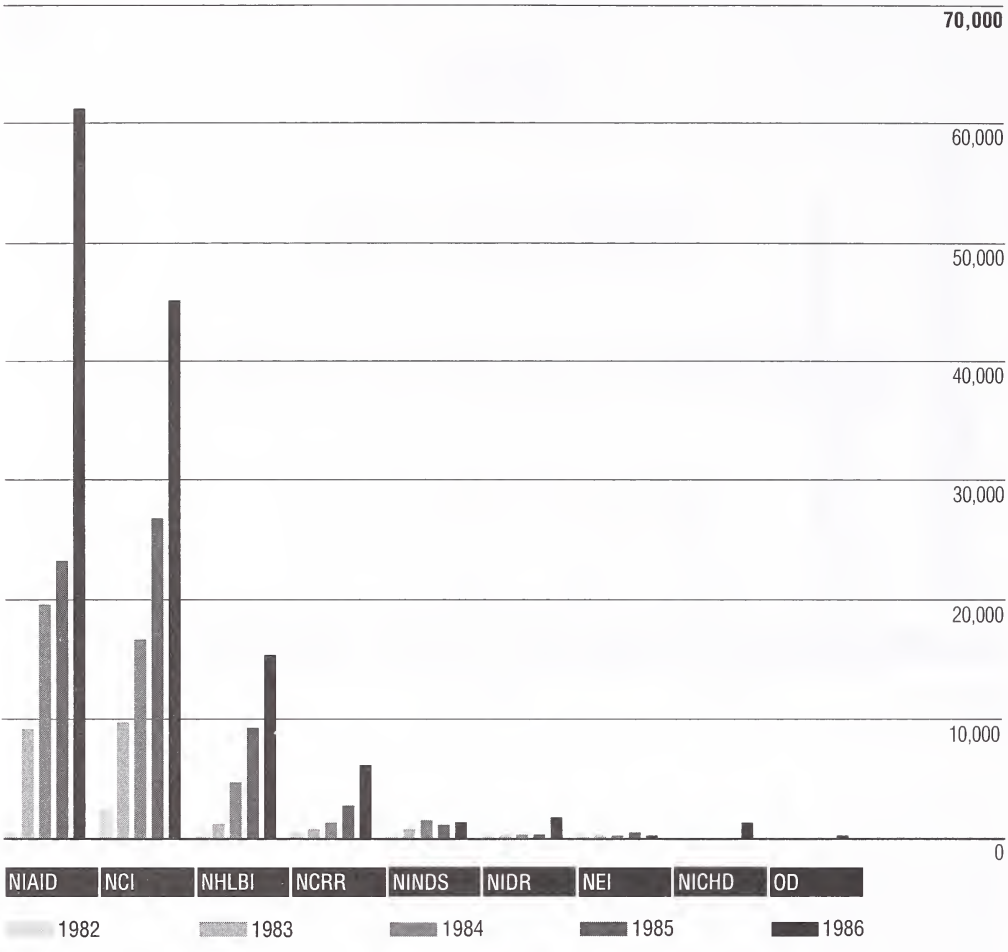


Source: NIH Data Book, 1992 (NIH Publication No. 92-1261)

excellence with the democratic imperative to ensure access of all groups to funding and to ensure accountability for expenditures of appropriated funds.[25] Major issues addressed included conflict of interest, inability to provide adequate review in highly specialized areas, concern that the review groups were not representative of the current trends in science, fear of missing the unrecognized genius by funding only "safe science," the volume of grants assigned to study section members, and the burden for both applicants and reviewers imposed by new laws and regulations.[26] None of these studies, it is worthy of note, considered the speed at which awards were made to be of great concern.[27] The NIH was thus surprised when AIDS activist groups and other critics decried the length of time it took for funding new grant proposals to study AIDS. As has been described elsewhere, it was as if the biomedical research community had spent four decades carefully crafting a great ocean liner, only to be asked why the ship would not fly.[28]

In the early 1980s, the extramural program utilized several different types of awards to fund research on AIDS.[29] In August 1982, the NCI issued its first request for investigators to submit grant applications relating specifically to AIDS.[30] This formal request was designed to bring into AIDS work those institutions that did not already participate in an NCI cooperative agreement, a funding mechanism similar to a grant, but one in which the awarding institute retained substantial programmatic involvement. Institutions already involved in cooperative agreements were eligible to apply for supplemental funds to inaugurate research on AIDS.[31] The NIAID had also begun to add AIDS monies to existing grants and to fund new awards. Before 1 October 1983, a program project grant on sexually transmitted diseases at the University of Washington was allocated just over $100,000

Figure 3. NIH AIDS Funding Profiles, FY 1982-86



Source: NIH Data Book

to expand its work to cover AIDS; a Georgetown University interdisciplinary research program on immunologic diseases was completely converted to study the AIDS problem; and new grants of varying sizes were made for a variety of studies, from laboratory and epidemiological research to assessing the psychosocial needs of AIDS patients.[32] Both the NCI and the NIAID also utilized the contract mechanism for some studies. The first NIAID contract, for example, was awarded to the New York Blood Center in fiscal year 1983 for the collection of specimens for detection of etiologic agents.[33]

NIH budget information, depicted graphically in Figures 2-4, reveals clearly how funding for AIDS has been divided among the NIH components.[34] These data encompass both extramural and intramural funding and cover fiscal years, which do not conform to calendar years but run from 1 October of the previous year to 30 September of the year given. Money designated for fiscal year 1990 may thus be released in October 1989. Figure 2, which includes appropriations for fiscal years 1982, 1983, and 1984, shows that in fiscal years 1982 and 1983, the National Cancer Institute led in AIDS funding, in large part

because of its keen interest in the problem of Kaposi's sarcoma. The NIAID also began to fund research on AIDS in 1982, although at first on a small scale in the intramural program.[35] The early AIDS funding in the National Institute of Dental Research (NIDR), the National Eye Institute (NEI), and the National Institute of Neurological Disorders and Stroke (NINDS—then called the National Institute of Neurological and Communicative Disorders and Stroke) also reflects intramural research and will be discussed below. In March 1983, the National Heart, Lung, and Blood Institute (NHLBI) was named the lead NIH institute to evaluate blood donor screening tests to reduce the risk of transmission of AIDS.[36] After the discovery of the AIDS virus in 1984, the NHLBI continued to collaborate with the Food and Drug Administration on tests to identify AIDS in the blood supply.

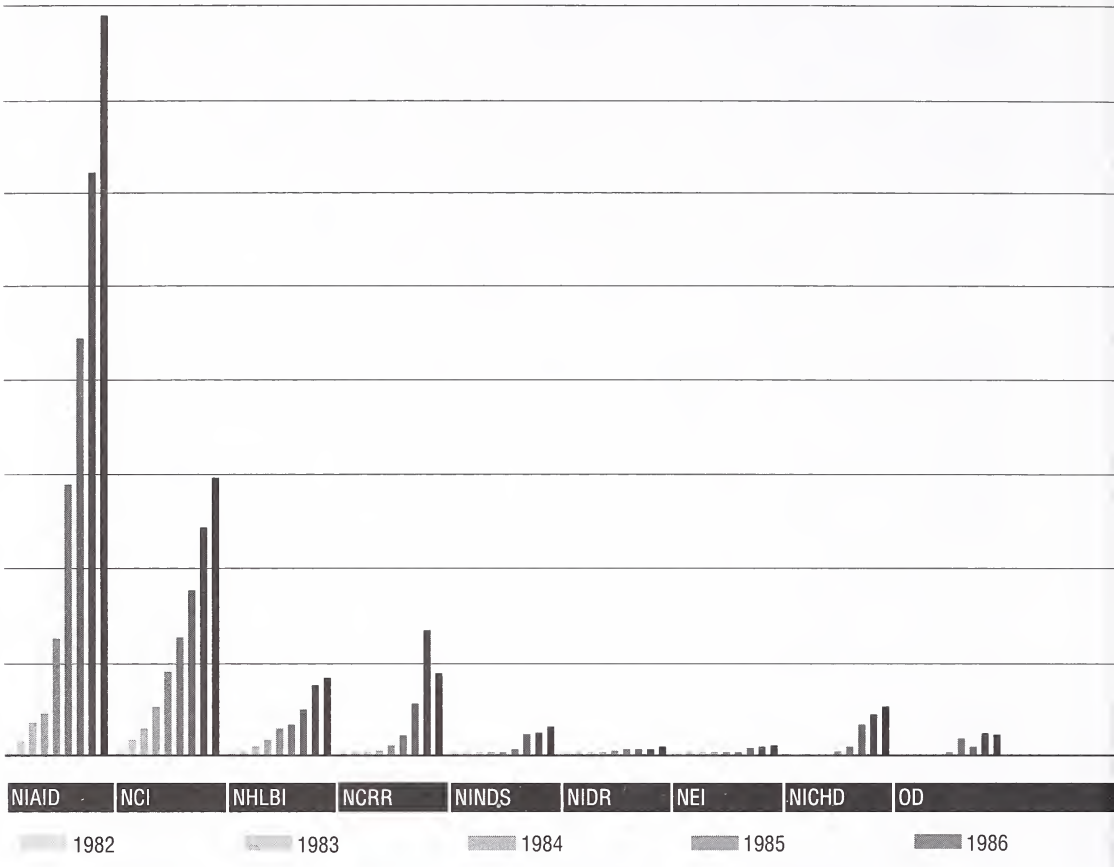
The final NIH component to become involved in this early period was the National Center for Research Resources (NCRR)—then called the Division of Research Resources—which funds, among other projects, the seven U.S. Regional Primate Centers.[37] In 1981, not long after AIDS was recognized in humans, a similar wasting syndrome was discovered among monkeys in three of the primate centers, California, Oregon, and New England. This disease was quickly named Simian Acquired Immunodeficiency Syndrome and usually referred to as Simian AIDS. Studies of Simian AIDS provided a model of immunodeficiency in primates. In addition, NCRR investigators attempted to transmit AIDS itself to primates at the Regional Centers in order to develop an animal model in which the disease could be studied and in which putative therapies and vaccines could be tested.[38]

Figure 3 adds fiscal years 1985 and 1986 to the AIDS funding profile. It reveals the spurt of work in the NIAID and in the NCI just after the AIDS virus was identified in 1984,[39] and the point in time—fiscal year 1986—when Congress expanded NIH funding for AIDS significantly. This is also when the NIAID assumed leadership of the NIH AIDS effort. Figure 4 updates the funding profile through fiscal year 1990 and shows how virtually all of the NIH institutes, including the Office of the Director (OD), established AIDS research programs. This figure also shows spikes in funding in 1989 and 1990 for the NCRR and the National Institute of Child Health and Human Development (NICHD). These represent the inauguration of large clinical and natural history studies, often in collaboration with other institutes.[40]

Response of the NIH Intramural Programs

Because the extramural program had been structured to move deliberately, it was the NIH intramural programs that in 1981 and 1982 were able to redirect resources most rapidly to investigate AIDS. Intramural AIDS efforts arose from individual initiative rather than in response to any top-down administrative directive and therein reflected traditional NIH reliance on investigator-initiated research. The first AIDS patient arrived at the NIH Clinical Center on 16 June 1981, eleven days after the initial report about the new syndrome was published in the *Morbidity and Mortality Weekly Report* from the CDC.[41] Thomas Waldmann, a distinguished NCI immunologist, admitted the referred patient under his Omnibus Metabolism Branch protocol. Waldmann and his associates attempted unsuccessfully to save the patient, who was beset by severe opportunistic infections and had essentially no immune response.[42] Almost exactly six months later, on 15 January 1982, a second AIDS patient arrived at the Clinical Center and was taken into the protocol on Human Immune Problems investigated by Anthony S. Fauci, then chief of the NIAID Laboratory of Immunoregulation.[43] For this and later patients, Fauci, his postdoctoral fellow H. Clifford Lane, and Henry Masur, Chief of Critical Care Medicine in the Clinical Center, formed a core team to study the pathogenesis of AIDS while they attempted the reconstitution of the

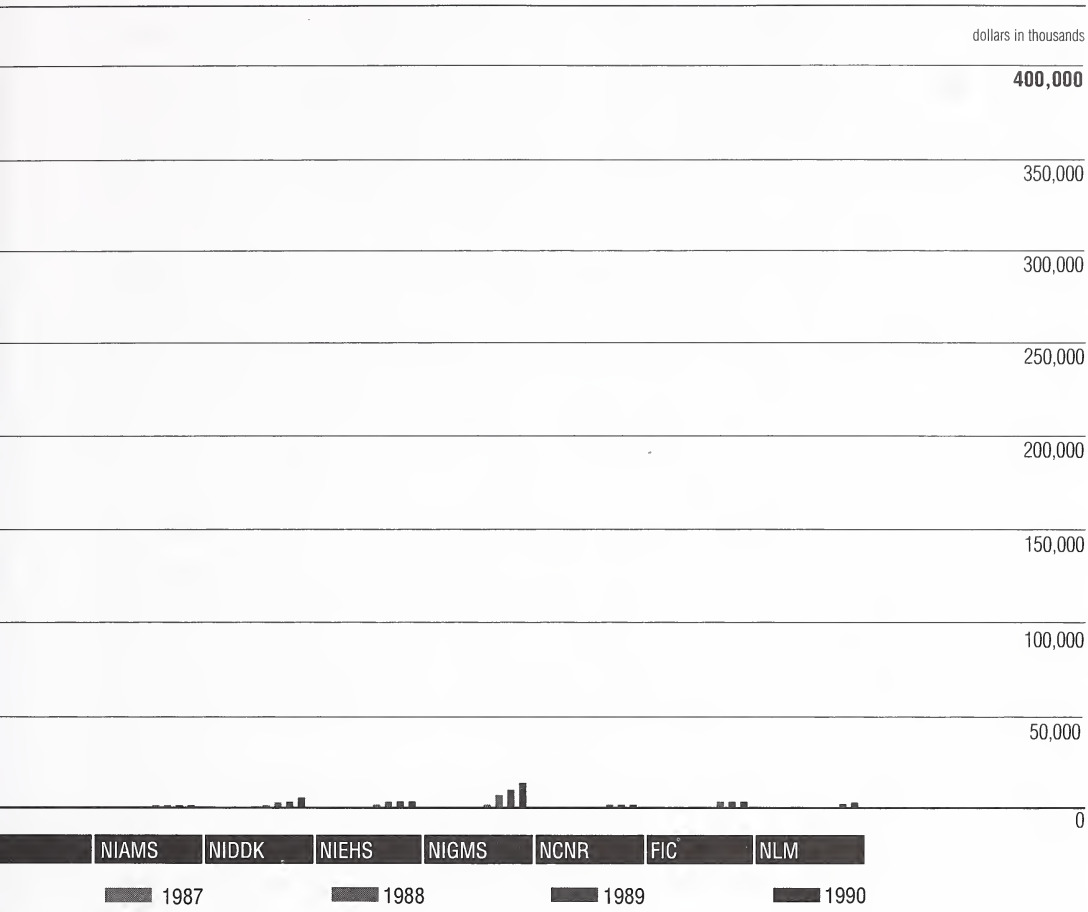
Figure 4. NIH AIDS Funding Profiles, FY 1982-90



Source: NIH Data Book

immune systems of AIDS patients, at first utilizing interferon and interleukin-2. They also took advantage of the fact that one AIDS patient had a healthy identical twin to transplant bone marrow from the healthy twin to the immunocompromised twin. Data showed definite improvement in the patient's immune system after the procedure, but the benefit soon disappeared and the patient died, suggesting that the causative factor in AIDS was not corrected but rather remained to infect and destroy the transplanted cells.[44] After the discovery of the AIDS virus, Fauci and the members of his laboratory modified their strategy to a two-pronged approach, adding antiviral therapies to immune reconstitution efforts.[45]

This group also established collaborations with other intramural experts in order to deal with the rare diseases suffered by AIDS patients. A group of investigators met weekly to review the information learned and to formulate new strategies.[46] Cytomegalovirus retinitis, which caused blindness and also attacked the gastrointestinal system, was one major concern. Robert B. Nussenblatt, Alan Palestine, and their NEI colleagues were thus enlisted to search for a drug that would control this opportunistic virus. The first drug tried was then known as DHPG, now called ganciclovir. It was chemically similar to acyclovir, which had recently been found effective against herpes virus infections.[47] Ganciclovir and foscar-



net, a later therapy studied by NEI, are the drugs of choice against cytomegalovirus infections in AIDS.[48]

NINDS investigators, including Nobel laureate D. Carleton Gajdusek, also joined the intramural clinical consultation to study neurological complications of AIDS, especially the so-called AIDS dementia.[49] NIDR scientists addressed the problems of AIDS patients who suffered oral candidiasis and oral Kaposi's sarcoma lesions.[50] Phillip Smith and Sharon Wahl of NIDR also demonstrated that macrophages and their precursors, monocytes, immune system scavengers that normally engulfed and destroyed foreign bacteria, were not able to migrate toward inflammatory stimulants in people infected with AIDS.[51]

As noted above, the National Cancer Institute took the lead in studying AIDS patients with Kaposi's sarcoma. The earliest intramural NCI activity in this area came out of a cancer epidemiology program that studied unusual clusters of cancer cases and traced family cancer connections. In the spring of 1981, one member of this group, James Goedert, was asked to consult on a diagnosis of Kaposi's sarcoma in a young man who was a friend of his family. After pronouncing that this would be impossible because Kaposi's "just didn't occur in young people," Goedert learned of other cases and, with others in his group, launched the first prospective epidemiological study of people at risk for AIDS. Since that time, this pro-

gram has expanded to include studies of how AIDS is transmitted from infected mothers to their babies.[52]

In 1982 and 1983 several other programs of note were initiated within the intramural program to facilitate research on AIDS. Michael Roberts of the NIDR issued recommendations to practicing dentists of precautionary procedures they should take in managing their patients with AIDS, and David K. Henderson, the hospital epidemiologist in the NIH Clinical Center issued precautions for health care workers that helped to minimize fear in the years before the cause of the disease had been determined.[53] The National Library of Medicine began to compile and publish an AIDS bibliography that is now also available as the computer database AIDSLINE, and Ruth Guyer, an immunologist on the staff of the NIAID intramural director, began editing and circulating and a newsletter called the *AIDS Memorandum*, which provided scientists a venue in which to share AIDS research findings rapidly and informally, without compromising their chances to publish in a mainstream journal. When the major professional journals began to publish articles on AIDS more quickly, this newsletter was discontinued.[54] In 1987, moreover, the Office of the Director instituted a targeted antiviral program aimed at utilizing the particular intramural expertise in structural biology and structural chemistry to a better understanding of the AIDS virus.[55] Intramural investigators submitted competitive applications like their extramural associates to be peer reviewed for funding under the OD targeted antiviral program. With these funds, X-ray crystallography, nuclear magnetic resonance, electron microscopy, and computer imaging processing studies were conducted to analyze the three-dimensional structure and organization of HIV proteins and to determine the shape of protein-bound drugs.[56]

Because of controversy surrounding it, the best known NIH research on AIDS may be that of Robert C. Gallo and his colleagues on etiology.[57] In his book, *Virus Hunting*, Gallo attributed his interest in research to find the AIDS agent to a 1982 seminar presented by James W. Curran, in which Curran cited epidemiological evidence indicating that AIDS was caused by a communicable pathogen with an affinity for helper T cells, which it then destroyed.[58] This intrigued Gallo, who had recently identified the first pathogenic human retrovirus, which also affected these cells. That retrovirus, however, caused helper T cells to proliferate uncontrollably rather than to die. Nonetheless, the affinity of the unknown pathogen for such a specific component of the immune system already known to be affected by one retrovirus suggested that a similar agent might cause AIDS. Gallo, Luc Montagnier at the Pasteur Institute in Paris and Jay Levy at the University of California, San Francisco, School of Medicine, all searched for, isolated, and characterized a retrovirus that has since come to be known as the Human Immunodeficiency Virus, or HIV.[59] By 1985 Gallo's laboratory also developed a test for AIDS called ELISA, or enzyme-linked immunosorbent assay.[60] It can be argued that this test, which is the initial assay used to safeguard the blood supply in the United States and in many other countries, has been to date the single most effective medical intervention in preventing new HIV infections.

With the discovery of an etiological agent, worldwide research on AIDS entered a short, intense period that lasted about two years during which the AIDS virus was characterized and evaluated to see whether therapies and/or vaccines could be quickly found to halt the epidemic. Intramural NIAID and NCI molecular biologists determined the genetic structure of HIV and discovered two of the virus's nine genes.[61] They also revealed the virus's propensity for genetic drift, which was much greater than that of the influenza virus. This meant that vaccine development might prove extremely difficult.[62] Even so, both the NIAID and the NCI launched vaccine development initiatives.[63]

Therapies for people with AIDS have focused on antiviral drugs, on efforts to reconsti-

tute the immune system, and on drugs to treat opportunistic infections and cancers. Virtually every antiviral AIDS drug was initially screened using the rapid in vitro assay developed by Samuel Broder and his intramural colleagues in the NCI.[64] Drugs that looked promising after this screening were then tested in animals and, if they appeared sufficiently nontoxic, became candidates for clinical trials. Many Phase I studies of AIDS drugs were conducted intramurally in the NIH Clinical Center.

Consequences of AIDS for the NIH

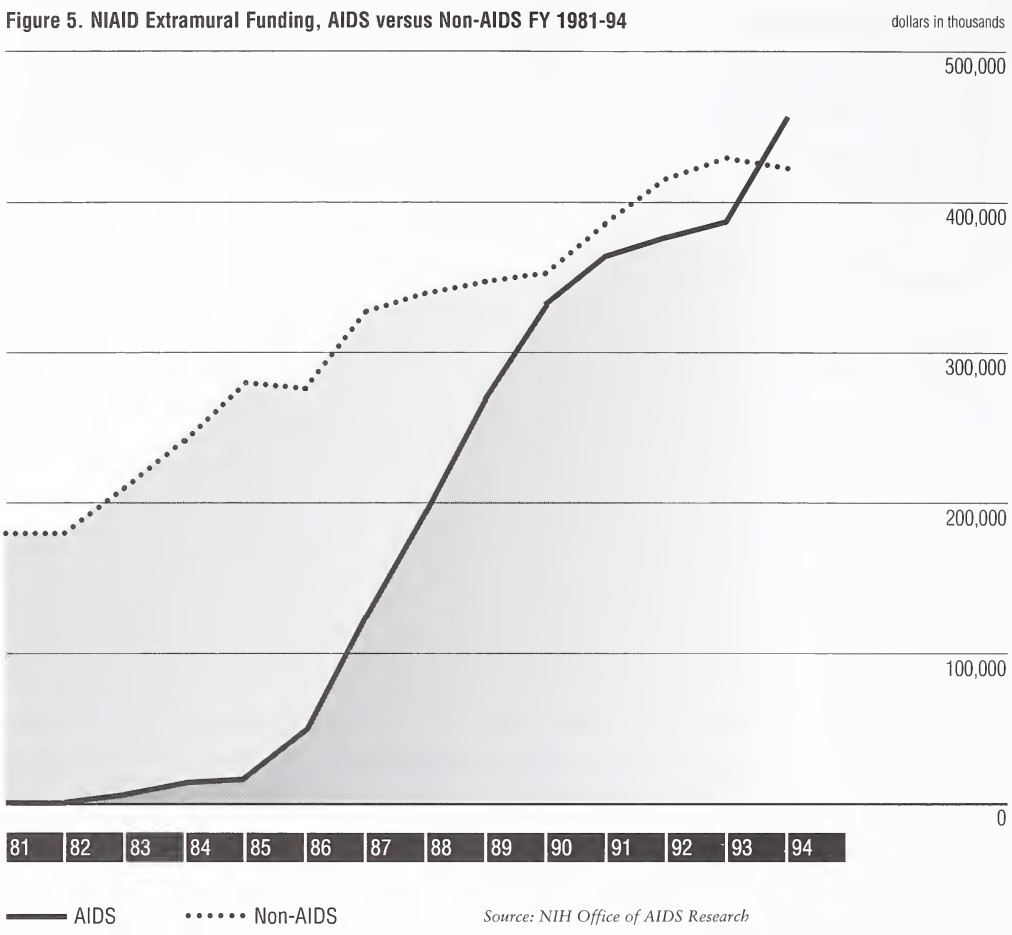
As the AIDS epidemic was unforeseen, so were its consequences for biomedical research at the NIH. One major consequence of AIDS has been the changes wrought by AIDS activists in the construction of clinical trials. People dying with AIDS believed that their immediate predicament warranted speedy access to putative therapies and discounted the importance of concerns over long-term side-effects.[65] Because the NIAID designed and ran clinical trials of AIDS drugs, AIDS groups brought pressure on the institute to change the way clinical trials were conducted. By October 1991 NIAID sponsored trials focused on three different approaches to treating the underlying immune deficiency in AIDS and the opportunistic infections and cancers. These included the standard clinical trial protocols known as the AIDS Clinical Trials Group; the Terry Beirn Community Programs for Clinical Research on AIDS, community-based studies that complement the ACTG; and the Division of AIDS Treatment Research Initiative, whose hallmark is speed in conducting "clinical trials and related research that evaluate new therapies and novel treatment approaches for those with HIV disease."[66]

A second consequence of AIDS was that traditional disease-related lobbying for increased research funds was transformed. AIDS activist groups were much more vocal and visible in demanding, not requesting, funding for AIDS than had been their earlier counterparts seeking funds for other diseases. Their efforts proved so successful that other groups, notably women with breast cancer and their families, have recently decided to base their crusade for funds on the AIDS model. "Since we are a crisis-oriented society," argued Sarah Fox, a professor of family medicine at the University of California, Los Angeles, "the people who make the most noise get the most publicity. Interest groups do count as opposed to data and rationality."[67]

A third consequence of AIDS has been to raise anew the debate over the best way to achieve medical breakthroughs: by developing a targeted approach and centralized direction or by the more traditional reliance on basic research and serendipitous observations of the individual investigator. For AIDS, calls for more emphasis on applied research have been couched as advocacy for an "AIDS research czar" or a "Manhattan Project" for AIDS.[68] In contrast, Barbara R. Jasny, a senior editor at *Science* magazine, emphasized in a recent issue the importance of continuing to investigate fundamental questions. She stated: "A cure may well come from an approach that has not been considered yet. Finding such an approach will require open-mindedness, a willingness to challenge accepted dogma, and a high degree of trust and collaboration among researchers from many disciplines, HIV-infected individuals, government, and industry."[69] With the enactment of the 1993 NIH Reauthorization Act, those advocating centralization have succeeded in requiring all new funds for AIDS to be funneled not to individual institutes but to the NIH Office of AIDS Research.

AIDS has also skewed research priorities significantly, especially within the NIAID. As funding for AIDS expanded in the early 1980s, many NIH grant applicants added AIDS as

Figure 5. NIAID Extramural Funding, AIDS versus Non-AIDS FY 1981-94



Source: NIH Office of AIDS Research

a project descriptor if any tenuous connection could be justified in order to increase, if only marginally, their chances for funding. As Figure 5 reveals, however, AIDS has grown to become an ever-larger portion of the NIAID budget. The 1994 estimate shows funding for AIDS as equaling or even surpassing funding for all other NIAID research combined.[70]

Conclusion

In a 1986 essay, historian Charles E. Rosenberg noted that "the great majority of Americans . . . look to the National Institutes of Health, not to the Bible, for ultimate deliverance from AIDS."[71] This observation reflects the key position that this federal agency has held since early in the AIDS epidemic and likewise demonstrates society's faith in "the authority of medicine and the truth of its agreed-upon knowledge," as Rosenberg stated.

This paper has sketched in broad strokes the NIH response to AIDS in its context as one of the agencies of the Public Health Service, each of which is charged with specific public health responsibilities, and within the NIH mission to discover new knowledge relating to health. NIH research—whether funded through the extramural programs or conducted within the intramural laboratories—has elucidated the etiology of AIDS, made headway in

describing the pathogenesis of the disease, informed efforts to develop therapies and vaccines, and produced a test to protect the blood supply. The unexpected budgetary and organizational consequences of responding to this disease have altered some aspects of the NIH response to AIDS but not its central role in funding and coordinating efforts to discover the information that will ultimately prevent or cure AIDS.

Notes

1. See Figure 1 for an organizational chart. The PHS health agencies were the Food and Drug Administration (FDA); the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the Centers for Disease Control (CDC); the Health Services Administration (HSA); the National Institutes of Health (NIH); and the Health Resources Administration (HRA).
2. On the history of the Food and Drug Administration, see James Harvey Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906* (Princeton, New Jersey: Princeton University Press, 1989); Charles O. Jackson, *Food and Drug Legislation in the New Deal* (Princeton, New Jersey: Princeton University Press, 1970).
3. Elizabeth W. Etheridge, *Sentinel for Health: A History of the Centers for Disease Control* (Berkeley: University of California Press, 1992).
4. National Institutes of Health, *NIH Almanac*, 1992 (Bethesda, Maryland: National Institutes of Health, NIH Publication No. 92-5), 1. On the history of the NIH see Victoria A. Harden, *Inventing the NIH: Federal Biomedical Research Policy, 1887-1937* (Baltimore, Maryland: Johns Hopkins University Press, 1986); G. Burroughs Mider, "The Federal Impact on Biomedical Research," in John Z. Bowers and Elizabeth F. Purcell, eds., *Advances in American Medicine: Essays at the Bicentennial*, 2 vols. (New York: Josiah Macy, Jr., Foundation, 1976), 2: 806-871; Stephen P. Strickland, *The Story of the NIH Grants Program* (Lanham, Maryland.: University Press of America, 1989); idem, *Politics, Science, and Dread Disease: A Short History of United States Medical Research Policy* (Cambridge, Massachusetts: Harvard University Press, 1972).
5. On the creation of the CDC, see Etheridge, *Sentinel for Health*, 16-17. On the history of the early antibiotic era, see Harry F. Dowling, *Fighting Infection: Conquests of the Twentieth Century* (Cambridge, Massachusetts: Harvard University Press, 1977); idem, *Medicines for Man: The Development, Regulation, and Use of Prescription Drugs* (New York: Alfred A. Knopf, 1970); John Parascandola, ed., *The History of Antibiotics: A Symposium* (Madison: University of Wisconsin Press, 1980); *Antibiotics Annual, 1958-1959* (New York: Medical Encyclopedia, 1959).
6. Etheridge, *Sentinel for Health*, 140-49, 168-177, 188-210; John R. Paul, *A History of Poliomyelitis* (New Haven, Connecticut: Yale University Press, 1971); Horace G. Ogden, *CDC and the Smallpox Crusade* (Washington, D.C.: Centers for Disease Control, 1987).
7. Etheridge, *Sentinel for Health*, 257-267, 305-307. After the organism that causes Legionnaires' disease was identified, the NIH became briefly involved in research on Legionnaires'. Research sponsored by the NIH fell into four categories: clarification of the etiology, elucidation of the mode of transmission, delineation of the pathology through the development of animal models, and characterization of different stains and surface antigens in order to develop diagnostic tests and possible vaccines. See Victoria A. Harden and Dennis Rodrigues, "Context for a new disease: aspects of biomedical research policy in the United States before AIDS," in Virginia Berridge and Philip Strong, eds., *AIDS and Contemporary History* (Cambridge: Cambridge University Press, 1993), 182-202, esp. Table 1, 188 and Figure I, 192.
8. Etheridge, *Sentinel for Health*, ch. 24, "The discovery of the AIDS epidemic," 321-340.
9. Memorandum, William H. Foege to Vincent T. DeVita, Jr., Re: Kaposi's sarcoma and opportunistic infections, 30 July 1981, file "Kaposi's sarcoma, 1981-1982," Division of Cancer Treatment files, National Cancer Institute, Bethesda, Maryland. Hereafter cited as DCT files, NCI.
10. Memorandum, Bruce Chabner, Acting Director, DCT, NCI to Director, Centers for Disease Control, Through Director, NCI, and Acting Director, NIH, Re: Kaposi's sarcoma conference, 6 August 1981, file "Kaposi's sarcoma, 1981-1982," DCT files, NCI.
11. Memorandum, Bruce Chabner to Director, Centers for Disease Control, Re: Kaposi's conference, 6 August 1981, file "Kaposi's sarcoma, 1981-1982," DCT files, NCI.
12. Summary of the workshop on Kaposi's sarcoma, sponsored by the Division of Cancer Treatment and the Division of Cancer Cause and Prevention, National Cancer Institute, and the Centers for Disease Control,

held 15 September 1981 at the National Institutes of Health, file "Kaposi's Sarcoma 1981-1982," Intramural Research 5-15, Office of the Director Central Files, NIH. Hereafter cited as OD files, NIH.

13. Memorandum, William A. Blattner to Acting Director, Division of Cancer Treatment, NCI, 13 October 1981, file "Kaposi's sarcoma, 1981-1982," DCT files, NCI.
14. Administrative Confidential Memorandum, Arthur S. Levine, Special Assistant for Scientific Coordination, DCT, NCI, to Director, NCI, through Acting Director, NCI, Re: Update on the epidemic of acquired immunodeficiency—Kaposi [sic] sarcoma—opportunistic infection, 2 July 1982, file "Kaposi's sarcoma 1981-1982," Intramural Research 5-15, OD files, NIH.
15. Ibid.
16. Memorandum, James B. Wyngaarden, Director, NIH, to Bureau/Institute/Division (BID) Directors, 13 July 1982, Re: Working Group on epidemic of acquired immunosuppression, opportunistic infections, and Kaposi's sarcoma; summary minutes of NIH Kaposi Sarcoma Working Group (KSWG), 20 July 1982, both in file "Kaposi's sarcoma, 1981-1982," Intramural Research 5-15, OD files, NIH. This group became known colloquially as the "Gordon committee," after its chairman, Robert S. Gordon, Jr.
17. Special Assistant to the Director, NIH, to "The Record," 25 May 1984, Re: First meeting of the PHS AIDS Executive Task Force, in Robert S. Gordon, Jr., Notebook, "PHS Executive Task Force on AIDS, 1984," NIH Historical Office.
18. NIH *Almanac*, 1992, 121-35. Intramural laboratories are also located in Hamilton, Montana; Research Triangle Park, North Carolina; Baltimore, Maryland; and Frederick, Maryland.
19. NIH *Almanac*, 1992, 111. The NIH extramural program provides nearly half the total federal basic research funding of universities and colleges in the United States. See National Institutes of Health, *NIH Data Book, 1992: Basic Data Relating to the National Institutes of Health* (Bethesda, Maryland: National Institutes of Health, NIH Publication No. 92-1261, 1992), 6.
20. National Institutes of Health, Office of Program Planning & Evaluation and the Division of Research Grants, *Basic Data Relating to the National Institutes of Health, 1981* (Bethesda, Maryland: National Institutes of Health, NIH Publication No. 81-1261, 1981), i.
21. These included cancer, heart disease, stroke, sickle-cell anemia, Cooley's anemia, arthritis, diabetes, epilepsy, sudden infant death syndrome, and multiple sclerosis. All initiatives and associated appropriations are listed in "Congressional Initiatives in Biomedical and Behavioral Research," in Appendix D, 36-38, 40, of U.S. President's Biomedical Research Panel, *Report of the President's Biomedical Research Panel*, 30 April 1976, 4 appendixes, 4 suppl. (Washington, D.C.: Government Printing Office, DHEW Publication Nos. (OS) 76-500 through 76-509, 1976).
22. Debra Jan Bibel, ed., *Milestones in Immunology: A Historical Exploration* (Madison, Wisconsin: Science Tech Publishers, 1988); Arthur M. Silverstein, *A History of Immunology* (San Diego, California: Academic Press, 1989); Pauline M. H. Mazumdar, ed., *Immunology, 1930-1980: Essays on the History of Immunology* (Toronto, Canada: Wall & Thompson, 1989).
23. In the intramural programs, there was also some duplication of epidemiological research and questions about cooperation between particular laboratories in the NIAID and in the NCI. See David G. Ostrow to Ginny Apuzzo, 24 April 1984, in Robert S. Gordon, Jr., Notebook, "Executive Task Force on AIDS, 1984," NIH Historical Office.
24. Catherine Henley, "Peer review of research grant applications at the National Institutes of Health, 1: The assignment and referral processes," *Federation Proceedings* 36(1977): 2066-2068; Henley, "Peer review of research grant applications at the National Institutes of Health, 2: Review by an initial review group," ibid., 2186-2190; Henley, "Peer review of research grant applications at the National Institutes of Health, 3: Review by an Advisory Board/Council," ibid., 2335-2338. On political questions relating to the peer review system, see Don K. Price, "Endless frontier or bureaucratic morass?" *Daedalus* 107(Spring 1978): 75-92.
25. Major studies of the NIH peer review system are summarized in "Selected Studies, Investigations, and Recommendations Related to the National Institutes of Health: An Annotated Bibliography," in Appendix D, "Selected Staff Papers," of U.S. President's Biomedical Research Panel, *Report of the President's Biomedical Research Panel*, 30 April 1976; 4 appendices, 4 suppl. (Washington, D.C.: Government Printing Office, DHEW Publication Nos. (OS) 76-500 through 76-509, 1976), 1-32.
26. For one example of discussions about peer review in the 1970s, see United States Congress, House, Committee on Appropriations, *Departments of Labor and Health, Education, and Welfare Appropriations for 1978: Hearings before a Subcommittee of the Committee on Appropriations*, part 3,

"National Institutes of Health," (Washington, D.C.: Government Printing Office, 1977), 56-57.

27. The only report in which I have found concern about the speed of the process was a General Accounting Office (GAO) study of grants made by the National Cancer Institute, which complained about "significant delays" in the funding process. See U.S. General Accounting Office, Comptroller General of the United States, *Administration of Contracts and Grants for Cancer Research, National Institutes of Health, Department of Health, Education, and Welfare B-164031(2)* (Washington, D.C.: General Accounting Office, 1971), 2-3. The National Cancer Act of 1971 (and later the National Heart, Blood Vessel, Lung, and Blood Act of 1972) authorized the NCI and the National Heart and Lung Institute to award grants up to $35,000 without review by the institute advisory councils. These small grants, however, were not exempted, as the GAO report had recommended, from peer review by scientific panels.
28. Harden and Rodrigues, "Context for a new disease," 190. See also Dennis Altman, *AIDS in the Mind of America* (Garden City, New York: Anchor Press/Doubleday, 1986), 48. For examples of criticism, see Sandra Panem, *The AIDS Bureaucracy* (Cambridge, Massachusetts: Harvard University Press, 1988), 5, 91-94; Randy Shilts, *And the Band Played On: Politics, People, and the AIDS Epidemic* (New York: St. Martin's Press, 1987), 93-95, 119-120.
29. Chronology of NIH activities in response to AIDS, prepared by the NIH Division of Legislative Activities, February 1984, in file "Kaposi's sarcoma, February 1984," Intramural Research 5-15, OD files, NIH.
30. National Cancer Institute, "Request for Cooperative Agreement Applications: RFA NIH-NCI-DCT-CTRP-82-13. Studies of AIDS (Kaposi's Sarcoma and Opportunistic Infections)," *NIH Guide for Grants and Contracts*, vol. 11, no. 9 (13 August 1982), 3-7.
31. William D. DeWys to Michael A. Friedman, 18 November 1981, file "Kaposi's sarcoma, 1981-1982" DCT files, NCI.
32. Grant awards information attached to Memorandum, Rosalind Gran, Division of Legislative Analysis, to James B. Wyngaarden, 24 February 1984, Re: NIH AIDS Activities—Information, file "Kaposi's sarcoma, February 1984," Intramural Research 5-15, OD files, NIH. A list of awards for fiscal years 1983 and 1984 by NIH institutes is in *Review of the Public Health Service's Response to AIDS: A Technical Memorandum* (Washington, D.C.: U.S. Congress, Office of Technology Assessment, OTA-TM-H-24, February 1985), 109-131.
33. Victoria A. Harden and Dennis Rodrigues, interview with Richard G. Wyatt, 28 March 1990, National Institutes of Health, Bethesda, Maryland, copy in NIH Historical Office; Moyer Material, Public Health Service Supplementary Budget Data, Justification of Appropriation Estimates for Committee on Appropriations, Fiscal Year 1985, 15, hereafter cited as Moyer Material for specific fiscal years.
34. Data on which these figures were prepared are from the NIH Office of AIDS Research and published in *NIH Data Book, 1992*, 20.
35. See below the discussion of Anthony S. Fauci's clinical work with AIDS patients in the intramural program during fiscal year 1982.
36. Memorandum, James B. Wyngaarden to Director, NHLBI, Re: Evaluation of blood donor screening tests to reduce risk of transmission of acquired immunodeficiency syndrome (AIDS), 14 March 1983, OD files, NIH; copy in Notebook on AIDS prepared by Amoz I. Chernoff, former chief, Division of Blood Resources, NHLBI, copy available in NIH Historical Office. See also Victoria A. Harden and Dennis Rodrigues, interview with Amoz I. Chernoff, 28 January 1993, Potomac, Maryland, copy in NIH Historical Office.
37. Leo A. Whitehair and William I. Gay, "The seven NIH Primate Research Centers," *Lab Animal* 10(1981): 26-34.
38. Moyer Material, FY 1985, 11; FY 1986, 16-17, 19; FY 1987, 18-19; William I. Gay, Notebook on AIDS activities of the National Center for Research Resources, copy in NIH Historical Office; Victoria A. Harden, interview with William I. Gay, 15 July 1992, National Institutes of Health, Bethesda, Maryland, copy in NIH Historical Office; C. J. Gibbs, Jr., D. C. Gajdusek, L. G. Epstein, D. M. Asher, Jaap Goudsmit, "Animal models of human disease: induction of persistent human T lymphotropic retrovirus infections in nonhuman primates and equines inoculated with tissues from AIDS patients or purified virus grown in vitro," in L. A. Salzman, ed., *Animal Models of Retrovirus Infection and Their Relationship to AIDS* (Orlando, Florida: Academic Press, 1986), 457-462.
39. Work on etiology is discussed in greater detail below.
40. Moyer Material, FY 1989, 35, 38.
41. "*Pneumocystis* pneumonia—Los Angeles," *Morbidity and Mortality Weekly Report* 30(5 June 1981):

250-252. Date of admission of the first NIH AIDS patient is noted in "NIH Response to AIDS," chronology prepared by the NIH Division of Legislative Analysis, 6 February 1984, attached to Note, Bel [Ceja] to Dr. Wyngaarden, Re: Response to Weiss ltr *(sic)* addressed to Dr. Brandt, 24 February 1984, file "Kaposi's sarcoma, February 1984," Intramural Research 5-15, OD files, NIH.

42. Victoria A. Harden and Dennis Rodrigues, interview with Thomas Waldmann, 14 March 1990, National Institutes of Health, Bethesda, Maryland, copy in the NIH Historical Office. Dr. Waldmann pointed out that, unfortunately, the medical record on the first AIDS patient disappeared after the patient's death, thus making it impossible to confirm certain specifics of his treatment. Comments on the multiple infections suffered by this patient as defined at autopsy are in Harden and Rodrigues, interview with Abe Macher, 29 April 1993, Rockville, Maryland, copy in the NIH Historical Office.
43. Victoria A. Harden and Dennis Rodrigues, interview with Anthony S. Fauci, 29 June 1993, National Institutes of Health, Bethesda, Maryland, copy in the NIH Historical Office. The date of admission is in Richard M. Krause to Edward N. Brandt, Jr., 15 January 1982, file "Kaposi's Sarcoma 1981-1982," Intramural Research 5-15, OD files, NIH.
44. The study also demonstrated the adoptive transfer of delayed-type hypersensitivity and an increase in the total number of peripheral blood helper T lymphocytes in the AIDS patient. See Fauci interview (n. 43); Victoria A. Harden and Dennis Rodrigues, interview with H. Clifford Lane, 12 March 1990, National Institutes of Health, Bethesda, Maryland, copy in the NIH Historical Office; Moyer Material, FY 1986, 18-19; A. H. Rook, Henry Masur, H. C. Lane, Winston Frederick, Tadashi Kasahara, A. M. Macher, J. Y. Djeu, J. F. Manischewitz, Lozannie Jackson, A. S. Fauci, and G. V. Quinnan, Jr., "Interleukin-2 enhances the depressed natural killer and cytomegalovirus-specific cytotoxic activities of lymphocytes from patients with the Acquired Immune Deficiency Syndrome," *Journal of Clinical Investigation* 72(1983): 398-403; H. C. Lane, Henry Masur, Alan Rook, L. C. Edgar, Gail Whalen, and A. S. Fauci, "Abnormalities of B cell activation and immunoregulation in patients with the Acquired Immunodeficiency Syndrome," *New England Journal of Medicine* 309(1983): 453-458.
45. A. S. Fauci and H. C. Lane, "Therapy of the Acquired Immunodeficiency Syndrome," in T. M. Baylers, M. C. Brain, and R. M. Cherniack, eds., *Current Therapy in Internal Medicine* (Philadelphia, Pennsylvania: B. C. Decker, 1983), 129-136. For an overview of current AIDS therapy, see A. S. Fauci, "Multifactorial nature of Human Immunodeficiency Virus disease: implications for therapy," *Science* 262(1993): 1011-1018.
46. The clinical collaborations are described in Lane interview (n. 44) and in Victoria A. Harden and Dennis Rodrigues, interview with Henry Masur, 22 November 1989, National Institutes of Health, Bethesda, Maryland, copy in the NIH Historical Office.
47. Victoria A. Harden and Dennis Rodrigues, interview with Robert B. Nussenblatt, 25 April 1990, National Institutes of Health, Bethesda, Maryland, copy in the NIH Historical Office; Moyer Material, FY 1986, 19, 22; FY 1987, 21-22; FY 1988, 9. See also the more general discussion of NEI contributions in Moyer Material, FY 1985, 17.
48. Nussenblatt interview; Moyer Material, FY 1990, 66; M. R. Rodrigues, Alan Palestine, R. B. Nussenblatt, Henry Masur, and Abe Macher, "Unilateral cytomegalovirus retinochorioditis and bilateral cystoid bodies in a bisexual male with the Acquired Immunodeficiency Syndrome," *Ophthalmology* 90(1983): 1577-1582; A. G. Palestine, Garth Stevens, Jr., H. C. Lane, Henry Masur, L. S. Fujikawa, R. B. Nussenblatt, A. H. Rook, and A. S. Mainschewitz, Barbara Baird, Margaret Megill, Gerald Quinnan, Edward Gelmann, A. S. Fauci, "Treatment of cytomegalovirus retinitis with dihydroxy propoxymethyl guanine," *American Journal of Ophthalmology* 101(1986): 95-101; Henry Masur, H. C. Lane, Alan Palestine, P. D. Smith, Jody Manischewitz, Garth Stevens, Jr., Leslie Fumikawa, A. M. Macher, Robert Nussenblatt, Barbara Baird, Margaret Megill, Alec Wittek, G. V. Quinnan, J. E. Parrillo, A. H. Rook, L. J. Eron, D. M. Poretz, R. I. Goldenberg, A. S. Fauci, and E. P. Gelmann, "Effect of 9-(1,3-dihydroxy-2-propoxymethyl) guanine on serious cytomegalovirus disease in eight immunosuppressed homosexual men," *Annals of Internal Medicine* 104(1986): 41-44; M. A. Polis, M. D. deSmet, B. F. Baird, Susan Mellow, Judith Falloon, R. T. Davey, Jr., J. A. Kovacs, A. G. Palestine, R. B. Nussenblatt, Henry Masur, H. C. Lane, "Increased survival of a cohort of patients with Acquired Immunodeficiency Syndrome and cytomegalovirus retinitis who received sodium phosphonoformate (Foscarnet)," *American Journal of Medicine* 94(1993): 175-180.
49. Moyer Material, FY 1985, 11; FY 1986, 16; G. M. Shaw, M. E. Harper, B. H. Hahn, L. G. Epstein, D. C. Gajdusek, R. W. Price, B. A. Navia, C. K. Petito, C. J. O'Hara, J. E. Groopman, E-S. Cho, J. M.

Oleske, Flossie Wong-Staal, R. C. Gallo, "HTLV-III infection in brains of children and adults with AIDS encephalopathy," *Science* 227(1985): 177-182.

50. NIDR investigators also studied the gastrointestinal manifestations of cytomegalovirus infection. See Moyer Material, FY 1985, 10; FY 1986, 14; FY 1987, 17.
51. Moyer Material, FY 1985, 10; FY 1986, 14; FY 1987, 17; P. D. Smith, Kiyoshi Ohura, Henry Masur, H. C. Lane, A. S. Fauci, S. M. Wahl, "Monocyte function in the Acquired Immune Deficiency Syndrome: defective chemotaxis," *Journal of Clinical Investigation* 74(1984): 2121-2128.
52. Victoria A. Harden and Dennis Rodrigues, interview with James J. Goedert, 10 March 1993; interview with William A. Blattner, 2 March 1990; interview with Robert Biggar, 6 November 1989, National Institutes of Health, Bethesda, Maryland, copies of all in NIH Historical Office. For a review of epidemiological studies, see J. J. Goedert and W. A. Blattner, "The epidemiology and natural history of Human Immunodeficiency Virus," in V. T. DeVita, Jr., S. Hellman, and A. A. Rosenberg, eds., *AIDS: Etiology, Diagnosis, Treatment, and Prevention*, 2nd ed. (Philadelphia, Pennsylvania: J. B. Lippincott, 1988), 33-60.
53. Moyer Material, FY 1985, 10; FY 1986, 15; Minutes of the Medical Board of the NIH Clinical Center, 6 July 1982, 4, manuscript collection, National Library of Medicine.
54. Moyer Material, FY 1985, 16. NLM's AIDS bibliography was initiated in June 1982. By May 1983, 179 citations to AIDS published between January 1980 and April 1983 had been compiled. See NIH Historical Office AIDS Chronology File; National Library of Medicine, "Acquired Immunodeficiency Syndrome (AIDS)," January 1980 through April 1982, 179 citations, including addendum, prepared by Charlotte Kenton, *Literature Search*, no. 83-1. Copies of the *AIDS Memorandum* are in the manuscript collection, National Library of Medicine.
55. Moyer Material, FY 1990, 79; Associate Director for Extramural Affairs to Director, NIH, 20 November 1986, Re: NIH AIDS Targeted Antivirals Plan, Notebook, "AIDS Planning Session with the Director, NIH, February 1987," copy in NIH Historical Office.
56. Moyer Material, FY 1990, 55, 71.
57. There are many accounts, from various points of view, of the discovery of the AIDS virus. Some of the major ones include Robert C. Gallo and Luc Montagnier, "The chronology of AIDS research," *Nature* 326(1987): 435-436; idem, "AIDS in 1988," *Scientific American* 259(October 1988): 41-48; R. C. Gallo, *Virus Hunting: AIDS, Cancer, and the Human Retrovirus: A Story of Scientific Discovery* (New York: Basic Books, 1991), 127-204; John Crewdson, "The Great AIDS Quest," Special Report, *Chicago Tribune*, 19 November 1989, section 5. A recent perspective on the scientific community and controversy surrounding Gallo is in Freeman J. Dyson, "Science in trouble," *American Scholar* 62(1993): 513-525.
58. Gallo, *Virus Hunting*. In this book, Gallo did not provide a date for the seminar presented by Curran that inspired his research on the etiology of AIDS. In a private communication to the author, however, Curran stated that it was his presentation of AIDS epidemiological data to the National Cancer Advisory Board (NCAB) on 1 December 1982. Gallo, who had just won the Lasker award for his discovery of the first human retrovirus, was scheduled on the NCAB agenda to describe his award-winning work, but this presentation was preempted by Curran's talk on AIDS. Curran stated that as he talked with Gallo before the meeting, he encouraged Gallo to look for a viral agent that destroyed T cells. See "Presentations at the NCAB meeting 1 December 1982," file "Kaposi's sarcoma, 1981-1982," DCT files, NCI.
59. In May 1986, a multinational committee suggested in nearly simultaneous letters to *Science* and *Nature*, two international scientific journals of record, that the name Human Immunodeficiency Virus was a more descriptive and less cumbersome designation for the AIDS virus that either Gallo's or Montagnier's first designations. See John Coffin, Ashley Haase, J. A. Levy, Luc Montagnier, Steven Oroszlan, Natalie Teich, Howard Temin, Kumao Toyoshima, Harold Varmus, Peter Vogt, and Robin Weiss, "Human Immunodeficiency Viruses," *Science* 232(1986): 697; idem, "What to call the AIDS virus?" *Nature* 321(1986): 10.
60. Moyer Material, FY 1986, 5-6, 25; S. H. Weiss, J. J. Goedert, M. G. Sarngadharan, A. J. Bodner, R. C. Gallo, and W. A. Blattner, "Screening test for HTLV-III (AIDS agent) antibodies: specificity, sensitivity, and applications," *Journal of the American Medical Association* 253(1985): 221-225.
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65. Peter S. Arno and Karynh L. Feiden, *Against the Odds: The Story of AIDS Drug Development, Politics, and Profits* (New York: HarperCollins, 1992).
66. "Clinical trials for AIDS therapies," National Institute of Allergy and Infectious Diseases *Backgrounder*, June 1993.
67. Gina Kolata, "Rethinking the statistics of 'epidemic' breast cancer," *New York Times*, 28 February 1993, E4.
68. David Brown, "Bill seeks to coordinate NIH research on AIDS: skeptics fear proposal could slow progress," *Washington Post*, 22 February 1993, A4.
69. Barbara R. Jasny, "AIDS 1993: unanswered questions," *Science* 260(1993): 1219.
70. Figures were supplied by the budget office of the National Institute of Allergy and Infectious Diseases.
71. Charles E. Rosenberg, "Disease and social order in America: perceptions and expectations," *Milbank Quarterly* 64, supplement 1(1986): 34-55; reprinted in idem, *Explaining Epidemics and Other Studies in the History of Medicine* (Cambridge and New York: Cambridge University Press, 1992), quotation from p. 275.

AIDS and the FDA

James Harvey Young

The disease that came in 1982 to be called AIDS[1] began to infiltrate the nation's consciousness in the preceding year, the year in which Ronald Reagan became president. Reagan's antiregulatory stance influenced the manner in which the Food and Drug Administration (FDA) would confront the expanding AIDS epidemic in negative as well as possibly positive ways. The agency's appropriations and manpower kept declining through the eighties.[2] This would have posed problems even had the FDA's obligations remained the same. Pressures increased, however, because more duties were added by acts of Congress—32 new laws in the decade ending with 1990.[3] Moreover, expensive crisis situations exploded involving tampering, especially with Tylenol, but also ranging from black pepper to Girl Scout cookies.[4] To these were added what came to hold the highest priority: addressing the various dimensions of AIDS.

These mounting pressures took their toll, as did a scandal in the handling of generic drugs.[5] By the end of the decade, as a result, the FDA's reputation had suffered decline. Its stature and credibility, observed a former agency chief counsel, were "probably as low as at any time . . . in history."[6] Journalists described the FDA as "battered" and "demoralized."[7]

Despite these troubles, Food and Drug Administration personnel tackled their tasks involving AIDS, when convinced of the necessity, with conviction, compassion, and imagination, although certainly not without criticism. The FDA's first challenge concerned the safety of the blood supply, an obligation the agency had been given when the modern blood banking industry arose in the 1940s.[8] The Centers for Disease Control (CDC), the FDA's companion agency in the Public Health Service, had discovered and defined the new disease and, early in 1982, had begun to fear that one route of its transmission might be through blood and blood products. A Floridian who took Factor VIII for hemophilia had died from the pneumonia that was the main opportunistic infection of the immune-destroying malady, and shortly the CDC learned of similar cases in Colorado and Ohio.[9] A baby born in San Francisco with a hemolytic disease was transfused and developed suspicious symptoms. Health officials checked the records of the nineteen donors and found one had AIDS.[10] The CDC assembled two meetings, one in Washington, the other in Atlanta, to warn those concerned with blood products, as donors, recipients, processors, and regulators, of the danger.[11] The indications that AIDS was blood-borne appeared so strong, CDC scientists asserted, that possible carriers should be discouraged from giving blood. Further, donated blood might be checked with a test for hepatitis antibodies, for many persons with the new disease also had suffered from the older one. The CDC's proposals, however, initially met a negative response. Their case did not seem proven scientifically. Blood was in short supply, and gay men were among the most faithful donors. Tests would be costly. The blood banking organizations were downright hostile, and their representatives dominated the FDA's Blood

Products Advisory Committee. The time for major regulatory steps had not yet come.

In retrospect, Bruce Evatt of the CDC, the first scientist to suggest that AIDS might be blood-borne, absolved the FDA of blame for not taking immediate action.[12] "We did not have proof . . .," he said, "we had epidemiological evidence suggesting it. The FDA makes recommendations that have to stand up in court."

The January 1983 meeting at the CDC, nonetheless, had an impact at the FDA. The agency had already, some months before, alerted its advisory committee that "specific measures affecting blood donors or transfusion therapy [might] become necessary."[13] Increasing cases of the fearful symptoms among hemophiliac patients prompted a meeting, FDA representatives participating, of the Public Health Service Task Force on AIDS to evaluate the significance of these reports.[14] Close liaison among Public Health Service agencies continued. Manufacturers of antihemophiliac concentrates were urged to develop means of reducing the infectivity of their products. The FDA began joint research with the National Heart, Lung, and Blood Institute to develop a protocol for chimpanzee testing of antihemophiliac products. The FDA held meetings with the American Red Cross, the American Association of Blood Banks, the National Hemophiliac Federation, and the National Gay Rights Task Force to discuss "the best methods of decreasing the potential of blood bank collecting from donors known to be at high risk of contracting or carrying AIDS."

With other agencies of the Public Health Service organized into an AIDS Task Force on Blood and Blood Products, the FDA developed recommendations, published in March 1983 in the CDC's *Morbidity and Mortality Weekly Report*, to prevent potential donors at high risk of AIDS from giving blood, either by their own initiative or by counsel from staff personnel at blood collecting establishments.[15] On the list were sexually active male homosexuals with multiple partners, recent Haitian immigrants, intravenous drug abusers, and sexual partners of persons known to have or suspected of having AIDS. Centers collecting plasma for use in manufacturing immune globulin and antihemophiliac clotting factor were advised to keep records of donors' weight, to examine volunteers for lymphadenopathy, and to sterilize blood products. Any plasma center flagrantly violating such counsel would be taken to court.[16]

Thus began a continuing regulatory regimen to protect blood for transfusion and as a source of treatment elements, especially for hemophiliacs.[17] The definition of suspect donors, as scientific and epidemiological knowledge accumulated, required annual revision.[18] In 1986, for example, added to the list of those screened out were men and women who had been prostitutes since 1977 and men who had engaged prostitutes in the preceding six months.[19] In 1990 the Haitian community in Miami protested the FDA's decision to exclude all Haitians as donors, and there was displeasure expressed in Congress as well.[20] Shortly the FDA strengthened its donor deferral program, avoiding the necessity of excluding potential givers because of geographical or national origins.[21] All blood would be checked for the AIDS virus and other blood-borne diseases.

This step rested on the discovery in 1984 of the retrovirus responsible for AIDS and the ensuing invention of a series of screening tests to detect the retrovirus in blood. In March 1985, the FDA licensed the first ELISA test, an enzyme-linked immunosorbent assay, that would detect antibodies to AIDS antigens in blood.[22] The license permitted manufacture and distribution of the kit to the nation's 2300 blood banks and plasma centers, as well as to public health and private clinics and physicians. So sensitive that it gave some false positives, the test determination could be checked by a more reliable procedure, hitherto used only in research, the Western Blot test. ELISA permitted the FDA to set more rigorous screening rules for blood and plasma collection centers. Health and Human Services

Secretary Margaret Heckler asserted that such testing would make the blood supply, already "very safe" because of donor screening, even safer. The level of danger had fallen below that of many medical risks, like death from influenza or from pregnancy.[23]

More versions of the ELISA kit received licenses, followed by licensing of the Western Blot test, then new generations of devices of detection, one of which discovered the presence of HIV-1 by directly revealing the proteins, or antigens, of the virus.[24] Speedier tests also evolved. These advances improved regulatory control. Test kits devised for home use, however, did not meet with agency approval. A plan to mail in a drop of dried blood on paper and then receive the verdict by phone or mail seemed fraught with too many chances for error.[25] Moreover, should the diagnosis for infection be positive, the person required face-to-face counseling with an expert, not a phone talk with a promoter.

Meanwhile, the FDA made screening standards ever more stringent, requiring that potential donors be informed about risk factors both in writing and by face-to-face questioning.[26] The agency signed an agreement with the American Red Cross that bound the latter to standardize operating procedures in all its blood collecting units to make as sure as possible that no unsuitable blood be released inadvertently for transfusion.[27] The FDA also sponsored workshops on serologic testing and donor screening. And, having set the standards, the FDA undertook in 1988 to inspect every blood bank and plasma center each year instead of biennially.[28] In the first year, the results were mixed: while 11.5 percent of the units revealed "significant violations warranting regulatory action," no case that year was discovered in which blood confirmed to be contaminated had been distributed. The chances of contracting AIDS by transfusion were calculated in 1991 to be rarer than dying from an adverse reaction to penicillin.[29] Products made from blood were also deemed safe. The combination of careful collection and multiple processes for destroying the virus in plasma during manufacturing would, if the system functioned, virtually eliminate any risk of AIDS transmission.[30]

Despite the optimistic trends, FDA inspections revealed causes for concern across the map, from Albany to New Orleans, from Chapel Hill to Portland.[31] Deviations from good processing procedures required recall of risky blood already in distribution. Now and then a case of fraudulent record-keeping surfaced.[32] Establishment and product licenses were threatened, sometimes suspended, even revoked. Such revocation halted operations at the American Regional Blood Bank of the American Red Cross in Albany because of failure to correct serious deficiencies after repeated FDA warnings.[33] These circumstances prompted the agency to inspect the Red Cross facility in Washington in an attempt to determine whether national management was exercising adequate control over its network of centers. A task force was formed to evaluate the situation. Constant regulatory vigilance regarding the blood supply proved to be prudent policy.[34] Recurrent inspections of blood banks revealed repeated transgressions of the rules. In May 1993, FDA Commissioner David A. Kessler felt compelled to haul the American Red Cross into court, where a federal district judge formalized an agreement between the organization and the agency as to the steps that must be followed to prevent unsuitable blood products from being released or transfused.[35] Even with the utmost care, perfection seems not possible. To a national television audience in October 1993, Commissioner Kessler gave a terse summary of the relation of the blood supply to AIDS: "The risks are rare, but they're real."[36]

Risks extending beyond blood became apparent. The FDA learned of HIV being transmitted from donors to recipients of solid organ and tissue transplants.[37] Although donors had been screened for HIV, they had evidently not seroconverted at the time of the donations. The FDA conducted a public hearing on the issue in October 1991, and Senator Paul

Simon introduced a bill that would expand the agency's authority in this area.

If blood could convey HIV through transfusions, it posed a risk to health care workers and researchers required to handle it. For a while, the use of gloves by phlebotomists in drawing blood from donors was controversial, since evidence of risk was scant and since gloves might not protect.[38] But the CDC discovered twenty cases of professionals who had become infected with HIV.[39] Most instances involved accidents with needle sticks, but in four medical workers the virus entered their bodies through chapped or scratched skin. The FDA began research on gloves, tightened their good manufacturing procedure rules, and sought to educate manufacturers about the new requirements.[40] In research, gloves were manipulated at three stages, then tested with virus particles about one-quarter of the diameter of HIV, to see if the virus would pass through. Vinyl gloves, tested after much manipulation, permitted more leakage than did latex gloves. The agency established a water test and set failure limits: 2.5 percent of a lot for surgical gloves and 4.0 percent for examining gloves. When inspections revealed higher failure rates, that meant seizure for domestic products or a ban on imported gloves. The FDA also joined in the broader effort, as with a poster session at the Montreal International AIDS conference, to educate health care workers about the need for gloves. Other facets of the health care workplace received the agency's attention, for example, the possibility of device-related transmission of HIV through such things as needles, dental drills, and intravenous tubing.[41] Could designs be changed to decrease risk, and could better sterilization procedures be devised?

As to barrier products, the FDA's other major concern came to center on another fluid transmitter of HIV, semen. In April 1987, the agency launched a major survey of the condom industry.[42] Testing over 150,000 samples gathered randomly from 633 batches, the FDA reported that 11 percent of domestic lots and 21 percent of foreign lots had failed, meaning that 4 condoms out of every 1000 would permit excessive leakage.

Natural membrane condoms made from the cecum of lambs came off worst, permitting viral leakage to the extent that they provided an utterly unreliable barrier to the virus.[43] Initial tests suggested that no HIV passed through an intact latex condom.[44] One of the FDA's later tests seems so fanciful as to bring to mind angels dancing on the head of a pin.[45] A fluid containing HIV-sized fluorescent beads simulated semen containing HIV. Of 120 randomly chosen condoms, 11 permitted passage of the bead-containing fluid at rates of from .001 to .02 microliters a second, revealing that these condoms contained a few pores larger than the beads. The escape, however, would equal less than .1 percent of an average ejaculate. It was an assumption at the time that HIV infection required substantial amounts of virus, so even the "worst case" condom, even if it would not absolutely eliminate risk, would provide considerable protection against disease.

Using the 4 out of 1000 standard, the FDA intensified inspection.[46] Most bad American lots were recalled; a few lots were seized. Unsatisfactory foreign lots were refused admission. The inspection led to significant improvement in production. The FDA funded and engaged in numerous studies to determine how environmental storage and shipping conditions affected performance of condoms, and manufacturers began to label expiration dates and to evaluate various latex formulations.[47]

The FDA shared in the national Safe Sex educational campaign. In 1990, for example, the agency prepared a pamphlet, widely circulated, called *Condoms and Sexually Transmitted Diseases . . . Especially AIDS*.[48] Forthright and frank, the document favored abstinence and monogamy as preferable courses, but for those who engaged in "risky sexual behavior," gave explicit rules for proper condom use. Risks were starkly stated, and no absolute guarantees given, but the reader could not miss the clear message:

"A Condom Could Save Your Life!"

In due course, the FDA gave guidance on preclinical and clinical testing to manufacturers of female barrier devices.[49] After a recommendation of approval from the agency's Obstetrics and Gynecology panel, this new form of protection, the Reality Vaginal Pouch, reached the market.

Besides blood and barriers, the FDA had responsibility for the safety and efficacy of the nation's drugs. Products promoted with false and misleading health claims in their labeling could not legally move in interstate commerce or enter the country from abroad. Further, the agency acted as gatekeeper for new drugs: such a drug could not be marketed until its sponsor had proved to the FDA's satisfaction that the drug was safe, its benefits outweighing its risks, and useful for treating the conditions indicated in the labeling. Confronted with a new disease, at first not understood in its etiology, so ominous as to panic those afflicted, and frightening the broader public as well as intensifying several dimensions of prejudice, the FDA faced, with respect to drugs relating to AIDS, complex and perplexing problems.

After an initial shocked lull, quackery with respect to AIDS burst forth on many fronts. "AIDS is a quack's dream come true," a journalist wrote, "an incurable fatal disease surrounded by fear and ignorance."[50] "Practically every piece of snake oil that's ever been used for anything," noted another informed observer, "is being adapted for use in AIDS."[51] This pattern extended from discredited cancer schemes that had been exiled to clinics outside the nation's borders, like Laetrile in Mexico and Immunoaugmentative Therapy in the Bahamas, to conversational pitching by health food store employees as shown by investigations in Kansas City and Houston.[52] AIDS quickly won its own place on the spectrum of pseudoscience, "a jungle of truly questionable and quack products," as Commissioner Angelo J. Aponte of the New York Department of Consumer Affairs put it.[53] These included a congeries of herbal wares prescribed by unscrupulous urban practitioners or sold at country stores. There were also complex lifestyle regimens like that offered in California at the Institute for Thermobaric Studies, where the routine treatment included a diet strong on organically grown vegetables, breathing and stretching exercises, avoiding clothing containing synthetic fabrics, taking tepid baths, and keeping cool by drinking up to three gallons of ionized water a day.[54]

The weakening immunity associated with AIDS had been recognized almost immediately. When research revealed the offending retrovirus, the pattern of quackery changed, backing off from flagrant promises of prevention and cure of AIDS, indeed, often leaving the word unmentioned, and stressing instead the boosting and restoration of immunity.[55] The promoters of numerous over-the-counter drugs and food supplements adopted this approach, and new ventures proliferated, like a product claiming to be bottled T cells, capsules containing such heavy metals as lead and chromium, and a device called the toastervisor, a bed of coils with low-amperage current on which one lay to strengthen immune competence.[56]

AIDS quackery's worst extreme may be suggested by merely listing injectables promoted as of benefit for AIDS: amino acids, blood serum, cells from fetal animals, DMSO, Easter lily bulbs, hydrogen peroxide, ozone, polio vaccine, pond scum, snake venom, typhoid vaccine, vitamins in megadoses, and the sufferer's own filtered urine.[57]

When AIDS arrived, combatting health fraud held a low priority among FDA responsibilities. In 1984, a Congressional committee pointed to the distressing fact that less than .001 percent of the agency's budget was devoted to the control of quackery.[58] The year before, the FDA had persuaded two marketers to refrain from labeling their preparations, vitamins and minerals, as treatments for AIDS.[59] As such frauds expanded, so too did FDA efforts to expose and contain them.

Education received more emphasis than regulation. Many of the most egregious frauds lay out of the FDA's grasp: outside the nation's borders, within states, as part of medical practice. Enforcement actions could be expensive. But when provocation seemed sufficient, as a deputy commissioner put it, the FDA did wield its "big guns—regulatory actions and criminal prosecutions."[60]

The FDA carried its message about the threat of fraudulent AIDS promotions in its own publications, *FDA Consumer*, and, for health professionals, the *Drug Bulletin*, and issued health fraud news releases and talk papers.[61] The agency revived and expanded antiquackery networks that had flourished in the 1960s but had dwindled in the 1970s, the FDA playing the roles, one official said, of "marriage broker and cheerleader."[62] One of these networks, involving the FDA with the Federal Trade Commission, the Postal Service, and the National Association of Consumer Agency Administrators, exchanged a constant flow of pertinent information. An alliance between the FDA and the Council of Better Business Bureaus led to pamphlets widely circulated among susceptible groups warning of "false hope from fraudulent treatments."[63] Liaison tightened between the FDA and state and local food and drug officials, as well as with state attorneys general.[64]

The FDA served as primary sponsor for a National Health Fraud Conference held in Kansas City during March 1988 at which AIDS fraud received systematic and severe exposure, conveyed to the nation by wide press coverage.[65] After the conference, to monitor better what was happening, the FDA began establishing AIDS Fraud Task Forces in the areas of the nation that accounted for 90 percent of the AIDS cases.[66] State and federal officials joined with private individuals, including members of the AIDS community, both to secure prompt detection of suspicious promotions and to convey warnings about fraud to health agencies throughout the nation.

Besides issuing words of warning, the FDA was forced to flex its regulatory muscle. A number of products trafficked in nonoxynol-9, earlier approved as a spermicide by the agency, that the Centers for Disease Control had later found to be lethal to the AIDS virus in vitro.[67] Promoters began to vend creams and condom lubricants containing the compound, making excessive claims of in vivo efficacy to keep AIDS at bay. Lubraseptic, one of these products, promoted with the slogan "Don't give up the pleasure. Reduce the risk," was seized by the FDA on misbranding charges, and, after a court proceeding, destroyed.

The same fate befell several dosage forms of colostrum, the first milk of cows that have just given birth, claimed as an immunity enhancer and a cure for a number of dread diseases, including AIDS.[68] Also seized was the common food preservative, BHT (butylated hydroxytoluene), promoted by Life Extension Products in Florida as an AIDS treatment.[69]

Another of the FDA's regulatory options, an Import Alert, sought to bar from entering the country Lawrence Burton's Immunoaugmentative Therapy (IAT), a blood serum prepared and administered by injection mostly in the Bahamas.[70] An alleged cancer cure and immune booster, the serum also began to be touted as a cure for AIDS. In 1985, scientists at Washington State University discovered that some vials of imported IAT showed the presence of the antibody to the HIV virus, a fact confirmed by the CDC, which also found live virus in one serum sample. The National Cancer Institute (NCI) discovered that half of another assortment of vials was possibly contaminated with the virus. The FDA issued an Import Alert, directing Customs and Postal Service authorities to detain all IAT vials brought or sent to the nation's borders.

Another weapon in the FDA's antiquackery arsenal, the injunction, has also been fired. After issuing a public warning about the dangers of using industrial grade hydrogen peroxide, even diluted, as an oral treatment for AIDS—a Texan had died from such therapy—

the FDA secured a judgment enjoining a Wisconsin concern, Vital Health Products, from distributing misbranded products, including hydrogen peroxide, for AIDS and other dire ailments.[71] The injunction was affirmed, early in 1993, on appeal. A Minnesota promoter of hydrogen peroxide was similarly restrained.[72]

In Michigan, a district court judge enjoined the maker of a drug called CanCell, promoted to cure AIDS and cancer, from distributing it or any other drug that violated new drug, adulteration, or misbranding provisions of federal law.[73] The promoter, however, persisted until brought into court again in November 1992 and ordered again to stop his illegal trade or else face jail. The judge required him to notify all his customers that he could no longer supply them with CanCell. In reaction, the FDA's Detroit district office was bombarded with letters and phone calls from frightened, angry people venting their rage at the agency and at the judge.

This flurry of rebuke in response to an episode of quackery was small as compared with the massive outburst of criticism aimed at the Food and Drug Administration for striving to carry out the larger mission assigned to it by society through the Congress: to make sure that new medications entering the marketplace be safe and effective. The traditional methods of accomplishing these goals came to seem, not helpful, but maddeningly obstructive to those caught in the grip of a fearful new disease whose sentence, should not new remedies become quickly available, was dire, a wasting, painful, and relatively short passage to death.

Speed had not been a priority of the new drug approval process, but, instead, careful, cautious deliberation. In the dawn days of the chemotherapeutic revolution, a careless chemist at a small pharmaceutical plant had mixed the first sulfa drug with a poisonous solvent, diethylene glycol, bringing death to over a hundred people, most of them children, before FDA inspectors tracked down and removed the so-called elixir from drugstores and homes.[74] This widely publicized disaster helped get a languishing food, drug, and cosmetic bill enacted in 1938 and placed in that law the requirement that the FDA approve new drugs for safety prior to their marketing.[75]

Proof of efficacy was added in 1962 while another drug crisis, although again concerned with safety, held the headlines. The thalidomide fright, with its babies born deformed, was mainly a might-have-been in the United States, because a Food and Drug heroine, Frances Kelsey, had withheld the drug's approval.[76] The impact of thalidomide concern helped get another languishing drug bill, whose main sponsor was Senator Estes Kefauver of Tennessee, enacted by unanimous vote of both Senate and House. One of its key provisions required a new drug's sponsor to prove to the FDA's satisfaction with substantial evidence from adequate and well-controlled clinical trials that the drug was effective in treating indications for the medical uses listed in labeling and advertising.

With this law, the FDA understood its purpose as minimizing risk, accepting the trade-off of slower medical progress in exchange for more carefully supervised advances.[77] Testing methods required of industry by the FDA received Supreme Court endorsement.[78] As time passed, the path to drug approval lengthened and expanded in expense. By 1990, it took, on the average, twelve years and cost the sponsor 231 million dollars.[79] This proved, Harold Edgar and David Rothman have written, "how powerful the symbolic role of a nightmare case can be in the implementation of public policy." Note an irony in passing, that thalidomide, the drug whose banishment was responsible for the proof of efficacy requirements, may return to the therapeutic stage because of possible efficacy in treating AIDS.[80]

In the 1970s, a fierce debate developed over the so-called "drug lag," a slowness in the release of new drugs in the United States as compared with Europe, and, indeed, a shrinkage in the output of drugs possessing therapeutic significance.[81] Executives of pharmaceuti-

cal firms and like-minded scientists and economists, while granting that part of the problem lay in "new yardsticks of sophistication" in the science of drug discovery, put most of the blame on the FDA's alleged cumbersome and overcautious procedures.[82] Agency officials and their academic, consumerist, and congressional allies denied the charges, but the FDA, nonetheless, sought to implement procedural changes that would encourage innovation and expedite the drug approval process.[83] A new venture in this direction was launched in 1982.[84] Yet, as AIDS assailed America, some observers of the medicinal drug scene continued to define the FDA's posture as "prudence dynamics, safety to the ultimate."[85]

This "pharmacological Calvinism,"[86] however, had not remained unyielding. Early in the FDA's experience with the new drug approval process, the agency had begun the occasional release of experimental drugs to physicians for compassionate treatment of individual patients or small groups for whom no effective standard therapy was available.[87] In this way drugs to correct cardiac arrhythmias had been permitted extensive use. For cancer drugs developed at the National Cancer Institute, a formal Category C program designating promising drugs for early release to physicians prescribing for cancer patients had been initiated in 1976.[88] This experience provided precedent value when hope dawned that drugs of value for treating the dread new disease might be discovered and devised.

In the early days, people who acquired AIDS felt overwhelming despair at their lack of options, punctuated by bursts of desperate eagerness that a treatment, heard of through rumor, might work a miracle.[89] Some who could afford it flew to Paris to get injections of HPA-223, a French discovery under study at the Pasteur Institute, eventually proved lethal. Others less affluent smuggled in from Mexico two drugs, ribavirin and isoprinosine, made in but not legally for sale in the United States. The governmental scientific establishment that had so quickly dispelled the horror of Legionnaires' disease was not taking their affliction seriously, people with AIDS protested, thus proving prejudice against the gay community.[90] That part of government that approved new drugs, the Food and Drug Administration, because no official AIDS drugs were available, received the lion's share of blame. Commissioner Frank E. Young could argue in his agency's defense that the FDA did not originate new drugs but served as a "passive conduit" through which drugs passed for review when submitted by sponsors, either pharmaceutical manufacturers or the National Institutes of Health.[91] "The FDA is not recognizing," charged an AIDS activist, "that handling this episode requires bold leadership and changes in past policy."[92] Members of the AIDS Coalition to Unleash Power took more explicit aim: "Only *one* agency, the FDA, is actively blocking the delivery of promising drugs to people with full-blown AIDS and people with HIV infection. Other agencies sin by omission; they aren't doing enough. Only the FDA sins by commission; it is doing the wrong things, and they are deadly wrongs. And only the FDA has the power *under existing laws and regulations* to change directions and provide many of our demands *immediately*."[93] A fortnight following this critique, members of ACT UP picketed FDA headquarters in Rockville, some assuming corpse-like posture bearing signs with such messages as "I Died for the Sins of FDA" and "Killed by the System"[94] What AIDS activists wanted, argued Martin Delaney, who had founded Project Inform in San Francisco, was less concern about final proof of efficacy in FDA drug policy and more emphasis on treatment, early and wide release of drugs that had even a hint of promise.[95] A physician in New York, Mathilde Krim, cochair of the American Foundation for AIDS Research, observed: "There's a rebellion against doctors playing God by preventing you from having access to something you believe is good."[96]

The AIDS community thus brought great and continuing pressure, expressed in corrosive words and enacted in threatening street theater, upon the FDA to release new drugs

quickly so that dying patients could try them although their efficacy, even their safety, remained unproven.[97] At the same time, more direct influence would press the FDA in somewhat the same direction, coming from the President's Task Force on Regulatory Relief chaired by Vice-President George Bush. And the FDA did, step by step, relax its strict system for distributing new drugs, at least those for treating life-threatening diseases. To what degree change came as a result of the two-pronged pressure would be hard to divine. Food and Drug officials observed the evolving tragedy, were moved by the suffering, and let their feelings influence policy. Commissioner Young, at a House committee hearing, referred to his own recent experience with melanoma to make clear his awareness of how people react upon receipt of an ominous diagnosis.[98] "I'd rather err on being compassionate," he admitted on another occasion. The outside pressures, a journalist has suggested, helped move FDA officials in the direction they were already going, a judgment shared by Anthony Fauci of the National Institute of Allergy and Infectious Diseases.[99] Yet the commissioner and his associates could not let compassion cancel their obligations under the law. In making changes, they frequently reiterated the ultimate need to establish the safety and efficacy of new drugs, including those for AIDS.[100]

The two principles destined to mark the FDA's modification of its new drug evaluation process in response to the AIDS crisis, accelerated approval and expanded early access, were present in the first dramatic episode: the testing and release of AZT.[101] The name azidothymidine—hence AZT—at the beginning of the alphabet was later changed to zidovudine at alphabet's end, but AZT hung on in popular parlance. The drug was synthesized in 1964 by Jerome Howard with National Cancer Institute support as a possible cancer treatment but proved ineffective. In the early 1970s, German chemists showed that AZT could suppress marine retroviruses. In 1984, after announcement of the retroviral cause of AIDS, Samuel Broder of the NCI began screening chemicals to find those that might inhibit in vitro replication of the human immunodeficiency virus. The pharmaceutical firm Burroughs Wellcome submitted AZT to NCI, and one of Broder's team, Hiroaki Mitsuya, demonstrated that AZT performed this function. The manufacturer also had in vitro tests done at the FDA and Duke University. Animal toxicity studies had already begun, and on 15 June 1985, Burroughs Wellcome submitted an investigational new drug application to the FDA, the step necessary for launching human trials. The agency approved the plans described in this document in seven days. Phase 1 trials, mainly concerned with assessing a drug's safety, began three weeks later with 35 patients at the Clinical Center of the National Institutes of Health and at Duke and ran for six weeks. The results proved promising, so a Phase 2 trial was planned, a double-blind placebo-controlled study designed to test AZT for efficacy in a group of nearly 300 AIDS and ARC (AIDS-related complex) patients at 12 clinical centers around the country, also checking for short-term side effects. The trials began in February 1986 and were prematurely terminated in September. The customary Phase 3 trials with a larger group were declared unnecessary. A special Data and Safety Monitoring Board declared AZT's effectiveness already amply proven through the significantly higher survival rate of those taking the drug over those receiving a placebo. Also, those on AZT had fewer opportunistic infections and enhanced immune response. On the negative side, significant toxicity had been encountered. Immediately, participants who had been given the placebo were switched to AZT therapy. Burroughs Wellcome began processing the trial data to submit a new drug application for FDA approval to permit marketing of AZT. Reaching the FDA in batches, the application was completed in December, 20 linear feet of documentation with 175 pages to every inch.[102] The application was scrutinized during long hours of overtime by FDA experts on anti-viral drugs, led by Ellen C. Cooper, and was reviewed and

recommended by the agency's Anti-Infective Drugs Advisory Committee. In record time, 107 days after completion of the new drug application, less than two years after the drug had first been given to humans, the FDA approved AZT for marketing.

A month after the Phase 2 trial was halted, five months before the new drug application was approved, and while other controlled trials were being planned to evaluate AZT's merit at other stages of HIV infection and in other age groups, the FDA granted Burroughs Wellcome's application for a compassionate use permit to distribute AZT to AIDS patients.[103] At the same time, the agency announced that it intended to speed the approval process for other drugs for AIDS and its opportunistic infections, assigning them a new 1-AA priority, which meant immediate action, ahead of drugs for all other disease categories. AIDS drugs would also receive prompt consideration for status as Orphan Drugs under a 1983 law, providing their developers—as Burroughs Wellcome had received for AZT—tax and other financial incentives and a period of marketing exclusivity. Under the "treatment IND" (investigational new drug), Burroughs Wellcome supplied AZT to 4805 AIDS patients who had fallen prey to *Pneumocystis carinii* pneumonia (PCP).[104]

The special "treatment IND" for AZT became precedent and model for a general "treatment IND" developed the next year by the FDA.[105] This formalization of compassionate early release formed part of a general rewriting of investigational new drug regulations underway since 1983, a venture in which the Presidential Task Force on Regulatory Relief was involved. The final rule permitted drugs for life-threatening and serious diseases to be released only to physicians skilled in treating the appropriate ailments. Patients could have the drug prescribed only if no satisfactory alternative therapy existed. There were other restrictions. A drug's sponsor must request treatment IND status for a drug from the FDA, and the agency could refuse to grant it, a power needed to bar ineffective and too risky products. The firm must proceed with due diligence toward seeking new drug approval and must abstain from any promotion, although permitted to sell the drug to the extent necessary to recoup development costs. The regulation listed the diseases deemed immediately life-threatening, leading off with "Advanced cases of AIDS."

AIDS activists soon became disenchanted with this intended liberalization of drug release policy.[106] The restrictions seemed too severe. The FDA's interpretations appeared too stringent, barring drugs from treatment IND status out of doubt that the "may be effective" stipulation had been met or out of fear that patients, gaining easy access to a yet-unproven drug, would avoid enrolling in the more demanding clinical trials needed for final proof of efficacy and safety. Manufacturers would not take advantage of their opportunity, desiring to keep FDA inspectors out of their financial records and to keep themselves out of liability suits should a drug prove too toxic. The new rule certainly did not satisfy the AIDS community's passionate desire for promising therapy. A year after the regulation took effect, a drug to treat PCP, trimetrexate, was awarded treatment IND status. But a longer time elapsed before a drug to battle the AIDS virus itself achieved early release for a broad segment of the afflicted.[107]

In October 1988, prompted by a request from Vice-President and candidate-for-President Bush as chair of the Task Force, the FDA took further steps "to speed the availability of new therapies to desperately ill patients."[108] The rules developed became a new Subpart E of the agency's investigational new drug regulations. Widespread discussion with representatives of interested groups—members of the AIDS community, consumers, health professionals, academicians, industrialists—aided in formulating the new procedures. The central element in the plan—and again AZT experience served as precedent—consisted of earlier, closer, and continuous consultation between the FDA and the sponsor during the

entire course of a drug's development to assure that animal research and human clinical trials were most skillfully designed to achieve the needed knowledge. The FDA itself might even do some of the necessary research. This program might permit the elimination of the large and expensive Phase 3 trials, although postmarketing studies could be required. FDA assistant commissioner for regulatory affairs, William L. Schwemer, said the new policy moved the FDA, "the traditional 'gatekeeper,' into the roles of 'scout' [and] 'herdsman.'"[109] Commissioner Young chose a sports metaphor. "Up to this point," he explained, "we've been the baseball umpire at the end of the [drug approval] process. What this new process offers is that we'll also be the catcher, giving early signals whether the research is leading to something or not."[110] The commissioner predicted the new policies would cut approval time by a third to a half.[111] The change from an adversarial to a collaborative position between regulator and regulated occasioned some concern in the scientific community, as did, in the AIDS community, the timing of the change, during the final days of Bush's presidential campaign: was his conversion to helping with desperate diseases like theirs genuine?[112]

While these new regulations, designated Subpart E, were being put in final form, the FDA took another major step in expanding consumer access to drugs. The decision emerged from controversy concerning dextran sulfate, the latest in a series of unproven drugs smuggled into the country, distributed by underground clinics, and taken with great expectations of therapeutic merit by people with AIDS.[113] The FDA had shown great leniency with respect to the activities of these clinics and had largely disregarded the bringing into the country by returning travelers of individual use quotas of medicines obtained abroad. Dextran sulfate, however, shipped from Japan in vast quantities and in disguise, had received a mixed legal reception, some lots passing freely through Customs, other lots being seized by order of regional FDA officials. This Japanese drug, sold for two decades over-the-counter in Japan to thin blood and lower cholesterol had some credentials as a possible AIDS treatment. Scientists both in Japan and at the National Cancer Institute had found that the drug during in vitro tests stopped the spread of HIV between cells. Clinical trials to assess its in vivo value, however, had just begun. Leading AIDS activists in both San Francisco and New York chided the FDA on its inconsistent approach and, in a series of conference calls with high agency officials, reached agreement on the terms of a liberalized personal-use importation policy.

No entry in the *Federal Register* proclaimed the greater leniency. The new policy was announced in a lecture given by Commissioner Young before a Lesbian and Gay Health Convention and AIDS Forum in Boston in July 1988.[114] As Young began speaking, resentful members surrounded his rostrum assuming corpse-like poses, but his message changed the atmosphere and evoked a standing ovation. Its content was then conveyed to FDA field offices. The FDA retained authority to examine any drug shipment in Customs Office custody to prevent counterfeit, fraudulent, harmful, or misleadingly promoted health products from entering the country. With these barriers surmounted, a returning traveler could bring or—and this was new—a citizen could import by mail a personal use quota, defined as a three months' supply, of any drug desired. One more condition must be met: the person who would use the drug must supply the name and address of the American physician responsible for supervising the treatment.

The commissioner told his Boston audience that the new policy provided assurance "that FDA is not doing business as usual in its fight against AIDS."[115] He did not intend to rob of hope desperate people who confronted early death. Young's "bold departure" struck some AIDS researchers as unwarranted and hazardous to the public health; it opened a wide door for charlatans to enter, and it threatened the soundness of clinical

trials. The commissioner, one critic mused, must have been "temporarily insane."

Dextran sulfate, the drug that had precipitated the relaxed import policy, did not turn out to be an effective AIDS treatment.[116] Other products, greeted enthusiastically and used widely in the AIDS community and causing friction between activist leaders and the FDA, also proved to be therapeutic disappointments, for example, AL-721 and Compound Q.[117] A continuing grievance, moreover, to people with AIDS was what they deemed the meager and tardy outflow of products from the FDA's drug approval process. To be sure, some effective therapies for opportunistic infections and cancers had been released, one of them, aerosolized pentamidine as a preventive for PCP, having been validated in a new way, the FDA accepting as clinical trial evidence community-wide experiments in San Francisco and New York in which treatment played as central a role as evaluation.[118] Drugs to combat opportunistic infections, AIDS activists argued, needed greater attention still.[119] More urgent still, the FDA had in its pipeline a mounting number of drugs, even vaccines,[120] aimed at AIDS itself, which were not getting out. The treatment IND had not worked as well as predicted: the FDA had forecast ten to twenty drugs, mostly for AIDS, achieving this status in two years, but that had not happened.[121] Some new approach to accelerated approval and expanded early access must be found.

The parallel track concept came not from within the FDA. It was an idea that activists had been developing, as Anthony Fauci of the NIAID was well aware through his conversations with them.[122] Fauci believed the approach beneficial both to people with AIDS, who would receive early treatment with promising agents, and to the scientific community, because it would protect enrollment in clinical trials. During the summer of 1989, he endorsed the two-track plan in a lecture in San Francisco, thus, as an administration official, according it enhanced credibility. Commissioner Young accepted the proposal in principle. Details of policy were sharply debated at an August meeting, augmented by witnesses, of the FDA's Anti-Infective Drug Advisory Committee. A parallel-track working group, chosen by the Public Health Service National AIDS Program Office so as to represent major interest groups—the FDA, the NIH, patient advocates, research scientists, community physicians, the pharmaceutical industry—began work on a document.

Earlier AZT had pioneered the treatment IND plan before it was formalized in print. Now another drug, technically on treatment IND protocol, pioneered the pattern of parallel track before a document enunciating its principles came from the press. The drug this time was dideoxyinosine, for short, ddI, another of Samuel Broder's "babies," a nucleoside analogue, thus chemical cousin to AZT.[123] Broder had patented the drug and licensed it to Bristol Myers. Phase 1 trials showed promise, probably fewer side effects, so ddI won the sobriquet "AZT without tears." The AIDS underground found an alternate producer in Canada and began to smuggle the drug to eager users. To checkmate this risky venture, government scientists and regulators, as well as leading activists, urged Bristol Myers, and the company agreed, to accompany its formal clinical trials on the main track with release of ddI on a parallel track. Any patient could have the drug prescribed who did not meet eligibility rules for the clinical trials and who also had found AZT ineffective or who had suffered severe side effects while taking it. An effort was made to observe closely how the hundreds of people with AIDS fared who took ddI on the easier access protocol. DdI was fully approved in a year.[124]

As ddI experience accumulated on both tracks, the Public Health Service committee finished its work and published on 21 May 1990 its parallel track proposals that distinctly resembled what was happening with ddI.[125] Unlike treatment IND, parallel track applied only to AIDS and its opportunistic infections. Debate developed as to whether the old or the new policy would permit easier access to new therapies. Commissioner Young, soon to

leave his post at the FDA, held that the policy change and the ddI experience demonstrated the FDA's flexibility.[126]

If the succession of relaxations meant legitimate compassion to the commissioner and a welcome "shift in the ethical paradigm" to some AIDS activists,[127] to a number of research scientists the changes heralded disaster. "What some people might consider foot-dragging," asserted Arthur Caplan, director of the University of Minnesota's Center for Medical Ethics, "is what many of us consider basic scientific validation. It takes time, but the system should be designed to protect the public, not increase its risks."[128] "The path that the FDA has begun to travel," adjudged two Columbia University professors, ". . . from the treatment IND to the parallel tracks, all make apparent that AIDS activists have succeeded in doing what earlier critics of the FDA were unable to do, taking decisions of risks and benefits out of the hands of FDA staff and putting them into the hands of the patients and nonresearch establishment physicians."[129] To George J. Annas, professor of health law at Boston University School of Medicine, the "gold standard" of randomized clinical trials had been seriously depreciated.[130] "The AIDS epidemic," he insisted, ". . . has helped evade the distinction between experimentation and therapy; has threatened to transform . . . FDA from a consumer protection agency into a medical technology agency; and has put AIDS patients, already suffering from an incurable disease, at further risk of psychological, physical and financial exploitation by those who would sell them useless drugs."

The new commissioner, David Kessler, who took office in November 1990, did not concur in such criticism, believing instead that accelerated approval of new drugs could be accomplished without an unacceptable degree of risk to the public welfare. A physician and lawyer, who had managed a hospital, been dean of a medical school, and served as consultant for Senator Orrin Hatch's Labor and Human Resources Committee, Kessler had published in the *New England Journal of Medicine* a perceptive article on the treatment IND, favoring this innovative approach to making new medications available. It was due to his willingness to accept new methods of analyzing data, using surrogate markers and historical controls, that ddI was approved so quickly.[131]

The proposed policy statement of 1990 for establishing the parallel track system became final in April 1992 after slight revision by another diversified PHS working group had taken account of comments on the original proposal.[132] The recognition of risk inherent in such very early widespread usage of AIDS drugs, for which "the evidence of effectiveness . . . [was] less than that generally required for a Treatment IND," prompted special provisions permitting the FDA to halt or terminate a study should significant hazard to patients become evident. The policy statement made firmly clear that release of a drug on parallel track must not delay or compromise the "crucial" controlled trials needed for approval. Enrollment for the official trials should begin "prior to or simultaneously with release of [the] drug for expanded eligibility." Admission criteria to parallel track were made somewhat easier, and special emphasis was placed on reaching patients in "underserved populations" and "outside of urban centers." Physicians involved must collect information with the expectation that useful safety and efficacy data might emerge. Sponsors must pay costs, provide special monitoring, and develop educational programs for patients, physicians, and other caregivers.

In the same month, the FDA proposed three other initiatives to speed the release of new breakthrough drugs.[133] If AIDS activists had played a key role in pushing parallel track, the White House had figured prominently in advancing accelerated approval. Now George Bush was president, and his vice president, Daniel Quayle, headed the Competitiveness Council with the mission of easing regulatory burdens. The president, the vice president, the

secretary of Health and Human Services, and the Food and Drug commissioner each separately announced the three new proposals.[134]

First, the FDA adopted in broad principle the stance the agency had taken in approving ddI, a reliance on surrogate endpoints in clinical trials as sufficient evidence to predict clinical benefit to warrant a drug's approval. "For example," the document stated, "an anti-HIV drug might demonstrate that it could provide weight gain and reduce the frequency of opportunistic infections, even though evidence of an effect on long-term survival was not yet available."[135] For drugs approved in such a way, the FDA might restrict distribution "to certain facilities or to physicians with special training or experience." The agency also would require preclearance of promotional materials. And streamlined withdrawal procedures could be applied promptly should a drug fail or unduly threaten or should the manufacturing firm violate its specified obligations.

The second new initiative, termed "safety testing harmonization," permitted an exchange of safety data derived from animal testing among the United States, Japan, and the European Community.[136] The avoidance of duplicatory studies would curtail time and expense. The third step, to reduce the backlog of new drug applications and relieve the pressure on an agency still understaffed, would permit the FDA to contract with qualified experts in the private sector to review and analyze certain routine types of applications, subject to the agency's final scrutiny. Another relief from pressure, resulting in speed-up of the reviewing process, came in October when Congress passed and the president signed the Prescription Drug User Fee Act of 1992.[137] Manufacturers of drugs and biologics will pay to have their products evaluated, this money permitting the FDA to hire some hundreds of new drug reviewers and support staff. The combination of initiatives, the FDA projects, should let the agency cut review time for "standard" applications to a year and for "priority" applications—AIDS still in the most urgent category—to six months. Throughout the decade of involvement with AIDS, the FDA constantly revised its administrative structure to manage more efficiently its growing obligations, and it created an Office of AIDS Coordination to harmonize intra-agency policy and to maintain liaison with other governmental and private sector groups.[138]

Commissioner Kessler is convinced that the policies of accelerated approval and expanded access—what one analyst calls a "paradigm shift" in the FDA's procedures—can be handled to achieve therapeutic advantages without undue risk.[139] He acknowledges that somewhere down the line some unanticipated hazard will almost certainly manifest itself, but he is confident the process can catch the danger quickly and halt it. The benefits of the new system, he holds, well outweigh the risks.

Of course, new medicines must be submitted for review. The third of Broder's "babies," ddC, was approved under the new accelerated review regulation, and one drug has moved along the parallel track, another anti-viral agent, d4T (stavudine).[140]

A sense of gloom about the degree of effectiveness of the initial medicines for AIDS, an echo of the early despair, has been evoked by the joint British and French Concorde clinical trials.[141] That angry activist, Larry Kramer, titled a column: "AZT Is Shit."[142] Looking ahead, commentators assert, the view does not seem hopeful. Even at best, to cite Lawrence Corey and Thomas Fleming, "The war on AIDS will be an extended one, and drug therapy for HIV infection is only in its infancy."[143] Quoting William A. Haseltine: "Given what we know today, it cannot be predicted when, or even if, effective treatments and vaccines will be developed."[144] Whatever therapies are developed, the FDA stands ready to evaluate them speedily. The one significant change wrought by the AIDS epidemic in American institutions, concluded a National Research Council panel in 1993, lay in the regulation of drugs:

the greater access to experimental therapies gained by AIDS activists and the altered way in which the public has come to view drug testing and approval.[145]

Notes

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AIDS: Reflections on the Past, Considerations for the Future

Anthony S. Fauci

Since I am primarily a scientist, I would like to provide first my reflections on the past and some considerations for the future related to the science of the Human Immunodeficiency Virus (HIV) and the Acquired Immunodeficiency Syndrome (AIDS). In addition, as the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH), I will consider a number of administrative and policy issues that have shaped, and will continue to shape, our response to this epidemic.

Science

The "historical" aspects of the scientific approach to HIV and AIDS that I will consider are the following: the discovery of the etiologic agent—HIV; the molecular characterization of the virus; the development of screening and diagnostic tests; the development of antiretroviral agents; early natural history and epidemiologic studies; and the challenge of delineating the pathogenic mechanisms of HIV.

Based on previous experience with infectious microorganisms, it was the perception of both the scientific community and the general public that once the etiologic agent responsible for AIDS was discovered, both effective therapeutics and an effective vaccine would soon follow. However, when HIV was identified as a human retrovirus, the usual paradigms in human virology were not entirely applicable. A unique aspect of the life cycle of a retrovirus is that it inserts itself within the genome of a cell and can remain latent without expression for the lifetime of the infected cell. The normal immune mechanisms which screen extracellular virions and viral proteins that are expressed on the surface of the host cell do not recognize virus that is buried in the genome of the cell. This aspect of the retroviral life cycle together with the high capacity of the virus to mutate have made the discovery of effective therapeutics and vaccines extremely problematic.

The process of molecular characterization of the virus began soon after HIV was identified as the etiologic agent responsible for AIDS. No other virus has been as intensively studied as HIV. Figure 1 represents the genomic map of HIV. HIV has three structural and at least six regulatory genes. The ultimate goal of the molecular characterization of HIV was to gain insight into the mechanisms by which HIV regulates its replication and ultimately destroys the body's immune system.

The development of screening and diagnostic tests and antiretroviral agents followed relatively soon after the discovery of HIV-1 and its early molecular characterization. The development of screening and diagnostic tests was a scientific breakthrough for three reasons. First, tests were utilized to screen blood and blood products to insure the safety of the

nation's blood supply. Second, scientists utilized the tests in epidemiologic and demographic studies to delineate the magnitude and scope of the HIV epidemic. Third, the tests were incorporated into clinical practice to diagnose individual patients with HIV infection.

The development of antiretroviral agents was also an important step forward. There are currently three antiretroviral drugs approved by the Food and Drug Administration—zidovudine (AZT), didanosine (ddI) and zalcitabine (ddC). The initial hope for antiretroviral agents was that they would suppress the replication of the virus and allow for the spontaneous regeneration of the immune reponse. Data from early studies demonstrated that AZT therapy did extend life and led to a decrease in the number of disease events in persons with symptomatic HIV infection or AIDS. Data from subsequent studies further indicated that AZT prolonged the disease free state in individuals with asymptomatic HIV infection with CD4+ T cell counts between 200/mm^3 and 500/mm^3. The confusion about the utility of antiretroviral therapy began with the announcement of the preliminary results of the joint British and French Concorde study at the International AIDS Conference in Berlin in the summer of 1993. The Concorde investigators concluded that, at the end of a three-year period, there was no significant difference in the survival time of asymptomatic patients treated with AZT early in their infection as compared to patients treated with AZT at the onset of symptomatic disease.[1] The results of the Concorde study were misinterpreted by some as indicating that AZT was ineffective under all circumstances. In fact, preliminary results supported the continuation of prescribing AZT for persons with symptomatic HIV disease, but appropriately brought into question the utility of early intervention with an antiretroviral agent whose beneficial effects were only temporary and that had known toxicities.

The initial natural history and epidemiologic studies of the evolving AIDS epidemic came in the form of reports issued by the Centers for Disease Control (CDC). The first reports of AIDS were among clusters of homosexual men.[2] This led to a number of hypotheses including the possibility that poppers inhaled by gay men or the allogeneic effect of semen when introduced into the rectum were responsible for initiating and propagating the disease. In December 1981, I wrote an editorial for the *Annals of Internal Medicine* entitled, "The Syndrome of Kaposi's Sarcoma and Opportunistic Infections: An Epidemiologically Restricted Disorder of Immunoregulation."[3] At the time, most people felt that this was a disease that would remain restricted to homosexual men and perhaps injection drug users (IDUs). It was clear in my mind and in the minds of several of my colleagues that, although no microbe was yet identified, this was a sexually transmitted and

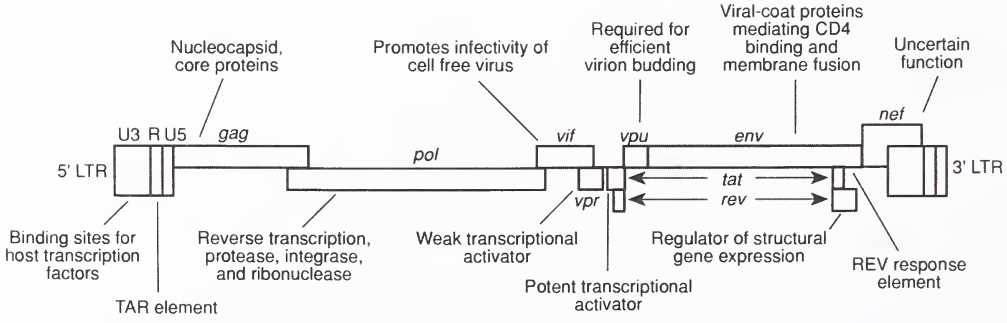

Figure 1. The genome of HIV. Reprinted by permission of Warner C. Greene and the *New England Journal of Medicine* 324(1991): 308.

blood borne infectious disease, and as such would not remain confined exclusively to any demographic group. Thus, at the close of the editorial I stated, "any assumption that the syndrome will remain restricted to a particular segment of our society is truly an assumption without scientific merit."[4] Unfortunately, I was soon proven to be correct as IDUs, blood and blood product recipients, heterosexuals, women and their children were identified as having symptoms similar to those in the initial reports.

Natural history and epidemiology studies have generated data to document and predict the various waves of HIV infection among different demographic groups in the United States and worldwide. Unfortunately, describing the epidemic in waves has lead some to believe that, since the epidemic wave has "peaked" in the homosexual community and is now accelerating in the disenfranchised injection drug using community, we no longer have to worry about HIV infection in the homosexual community. This assumption is inaccurate as indicated in recent reports from San Francisco that homosexual men, especially young homosexual men, continue to engage in behaviors that put them at risk for HIV infection.[5]

An important contribution of longitudinal natural history studies is that data have been accumulated on persons with HIV infection who have been well for more than ten years; some of these individuals have had virtually no deterioration of their immune system. Study of these individuals may provide important insights into the mechanisms of pathogenesis of HIV disease as well as information upon which to develop strategies for the design of therapeutic substances and vaccines.

The typical course of HIV infection (Figure 2) is marked by a cascade of complex phases from the initial infection followed usually by a long period of clinical latency lasting up to ten years during which time there is an insidious diminution of immune function culminating with the onset of clinical disease and death. The question of whether or not the virus was truly latent during the clinical latency phase has been the focus of attention in my

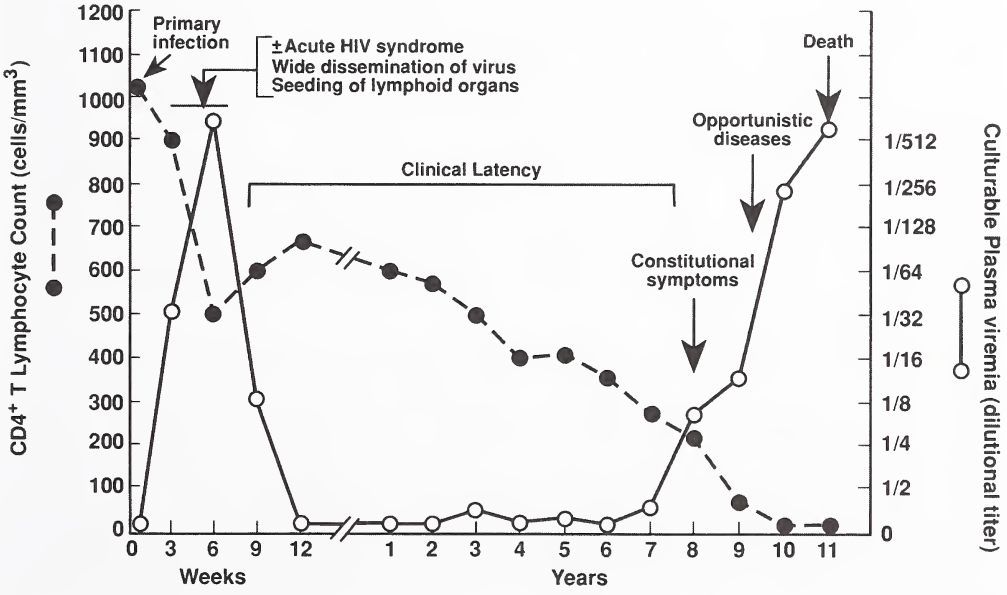

Figure 2. Typical course of HIV infection.

own laboratory for many years. My colleagues and I have been able to demonstrate that the virus replicates throughout the course of disease within the lymphoid tissue and that the microenvironment of the lymph nodes undergoes progressive destruction over the course of HIV disease.

Considerable progress has been made in the field of HIV research over the last twelve years; however, there are many important questions that remain unanswered.[6] An important challenge is to maintain a balance between caring for and treating the people who are already infected using currently available knowledge, while focusing our research efforts on understanding the complex pathogenic processes that may provide clues for the development of more effective therapeutics and a prophylactic vaccine for the future.

The topics that I would like to focus on in considering the future of HIV-related science are: the pathogenesis of HIV disease; the discovery and development of therapeutics and vaccines; and behavioral research. The pathogenic mechanisms of HIV disease are complex and multifactorial. We now know that, in addition to persistent virus replication in a person with HIV infection, there are various immunological phenomena such as immune activation, cytokine secretion, and disruption of the microenvironment of the immune system that occur as a consequence of HIV infection. The HIV virus is the primary initiator and propagator of disease; however, it is not only the virus that determines the progression of disease, it is also the manner in which the immune system responds to the virus that determines the course of HIV disease. Further elucidation of the immunopathogenesis of HIV is essential for the development of a comprehensive therapeutic approach to the patient.[7] Safer and more effective antiretroviral drugs are certainly needed. However, as we delineate more completely the complex pathogenic mechanisms of HIV disease, these may serve as appropriate targets for therapeutic intervention. For example, modulation of cytokine secretion, control of aberrant immune activation, and immunologic reconstitution should all be pursued as therapeutic possibilities.

The development of a safe and effective vaccine for HIV infection is quite problematic. There are a number of vaccine candidates in clinical trials to determine safety and immunogenicity. Two of these candidates have gone on to Phase II trials in a limited number of individuals with behaviors that would be considered to be high risk.[8] The next decision point is if and when to take either of these vaccine candidates or any other candidate into more comprehensive Phase III efficacy trials. None of the currently available vaccine candidates fulfill the classic criteria used to decide whether or not a candidate is ready for a Phase III trial.[9] In addition, the assays needed to determine if the candidates meet the traditional criteria are inadequate. Appropriate technology needs to be developed to generate answers to essential questions. Adding even more complexity to this decision-making process will be the legal, ethical, and social issues involved in vaccine research.

An important component of the AIDS research agenda is behavioral research. Areas of behavioral research that deserve attention in the future include: further determination of the spectrum and frequency of behaviors associated with risk of HIV infection; understanding the link between knowledge of HIV status and capacity for initiating and maintaining behavior change; and, enhancement of recruitment, retention, and protocol adherence in therapeutic and vaccine trials. In the absence of a safe and effective vaccine, modification of behavior is the only means of curtailing the spread of HIV infection worldwide. It is to be hoped that behavioral research will lead to improved approaches to effective behavioral modification.

Policy

As I made my scientific entry into the field of AIDS in 1981, I learned very quickly that it was impossible to separate HIV science from HIV policy. The convergence of these issues, in most respects, has had a net positive effect on both the policy making and scientific decision-making process. The successful integration of the two in the HIV arena may actually serve as a model for the role of science in policy making and the incorporation of important social elements into the scientific decision-making process.

Some of the policy issues that shaped our response to the HIV epidemic include: the interaction of science, politics, and society; the emergence of constituency activism; access to therapy; the drug approval process; and intense public and media interest.

The interaction between science, politics, and society set the tone for the early response to the AIDS epidemic. The temporal association of the AIDS epidemic and the gay empowerment movement serves as a good example of this interaction. Given the fact that early on, and even to some extent now, the AIDS epidemic was portrayed as epidemiologically restricted to homosexual men, there was a justifiable concern on behalf of the gay community that the gains in civil rights they had made during the 1970s might be jeopardized. This concern manifested itself inappropriately during the debates regarding the closure of the bathhouses in San Francisco. The attempt on the part of health officials in the city of San Francisco to close the baths, where behavioral patterns were contributing greatly to the spread of HIV infection, was seen by certain members of the gay community as an infringement of their civil rights, not as a public health measure. One of the most important products of the continual interaction of science, politics, and society in the AIDS epidemic has been the emergence of constituency activism.

The scientific community quickly learned the importance of including AIDS activists in the administrative policy decision-making process. Although the interaction between the activist and scientific communities was at first one of confrontation, AIDS activists became an invaluable resource in the design of clinical trials to make them "user friendly" for people with AIDS. Over the past twelve years, many AIDS activists have moved from acts of civil disobedience at the CDC, the Food and Drug Administration (FDA), and the National Institutes of Health to serving on national advisory boards and task forces within those same agencies.

The establishment of the parallel track mechanism for drug approval serves as an example of the positive effect of activism in AIDS policy. The idea of a parallel track mechanism emerged from the activist community as a solution to a number of problems. First, because there were so few therapeutic options for HIV-infected individuals, the demand for experimental therapy was greater than could be accommodated by the clinical trial system. Second, not all HIV-infected persons were eligible for clinical trials or had access to a clinical trial location. Third, many HIV-infected patients were obtaining therapy outside the clinical trial network which limited the effectiveness of the data collected by the clinical trial sites.

The idea behind parallel track was to create a mechanism by which experimental drugs would be available in parallel with but outside of an ongoing clinical trial. In a speech I made to a large group of activists in San Francisco in 1989, I presented a parallel track mechanism for clinical trials, incorporating the ideas of the activists into a formal process to provide parallel access to experimental drugs at the Phase II point in a clinical trial. The Phase II trial would continue through the traditional rigorous process while at the same time the drug being tested would be made available to others not able to participate in the trial.

In addition to generating intensive interest among AIDS activists, AIDS research has come under the heightened attention and scrutiny of the media. In most instances the media handling of the epidemic has had a positive effect. However, in certain cases, research find-

ings, however preliminary, were blown out of proportion and in other cases, public panics were unnecessarily triggered by exaggerated news reports. The media response to reports of a "new mystery virus," announced at the International AIDS Conference in Amsterdam in 1992, serves as an example of the negative effect of such scrutiny. Certain components of the media took a handful of reports of severely immunosuppressed people without HIV infection and turned it into a story of a failure of the disease surveillance system and even neglect on the part of the United States federal government in response to a public health crisis. One report in particular suggested that certain officials at the CDC resign for failing to recognize the "new AIDS epidemic." In fact, the syndrome, later identified as idiopathic CD4 T-lymphocytopenia (ICL), was not caused by a virus, but by multiple factors in a small number of isolated individuals and was not a cause for public alarm.[10]

With regard to policy issues in the future, there are several to consider including: the AIDS research budget; the "Manhattan Project" proposal; the changing demography of the epidemic; and the conflicting agendas among constituency groups.

Changes in the NIH budget for AIDS research tell a story about the biomedical research effort regarding the AIDS epidemic. After a rapid acceleration of funds due initially to congressional mandates and later to commitments made by the Executive Branch, there was a plateau in funding in the early 1990s as a result of budget constrictions across the federal government. Then, there was a substantial increase in AIDS research funding between Fiscal year 1993 and Fiscal year 1994. The Clinton Administration designated AIDS an "investment" area and has pledged to continue to provide additional funds for AIDS research despite severe constraints on other areas of biomedical research funding. Our ability to continue to fund ongoing initiatives at their current level and invest in new directions in AIDS research will depend on the size of future investments. The proposed "Manhattan Project" for AIDS may affect the funds available to invest in HIV research.

Most biomedical researchers feel that the science of HIV is not far enough along to mount a true "Manhattan Project." Creating a central location for AIDS researchers to search for a cure is not yet a viable scientific endeavor. "Manhattan-like Projects" that fund a small group of investigators to focus their scientific efforts on a particular research question may be a more practical alternative. Initiating such a program would require an additional investment of funds or re-directing funds from ongoing projects. It would be important not to divert funds from worthy ongoing research in order to embark prematurely upon a "directed" project of uncertain benefit.

As was indicated, the HIV epidemic has affected certain demographic groups in waves. First, the disease affected predominantly homosexual and bisexual men followed by an increase in the numbers of cases in injection drug users. The current wave of infection is affecting heterosexuals, particularly women and their children, among the disenfranchised inner city minority population. In this regard, the epidemic has moved from a politically astute community into communities that have traditionally had very little political voice or power. This change in demography has created some conflict among AIDS related constituency groups. Rather than joining forces behind a uniform set of priorities, certain AIDS constituency groups have become fragmented. It will be important for these groups to unify behind the concept that HIV disease does not discriminate and combine their expertise effectively to prevent and treat this disease.

From my perspective as a physician, a scientist, and a science administrator, AIDS has had an extraordinary and historic impact on the manner in which scientists, health care providers, government administrators and regulators, and constituency groups interact. The process has been enlightening and on the whole positive and productive. The influence of

this paradigm is already being felt in other diseases. It is to be hoped that this epidemic will come under control and lasting solutions in the form of effective therapies and vaccines will allow us to reflect with a new perspective on the events of these extraordinary years.

Notes

1. Jean-Pierre Aboulker and Ann Marie Swart, Letter to the editor, "Preliminary analysis of the Concorde trial," *Lancet* 341(3 April 1993): 889-890.
2. Michael Gottlieb et al., "*Pneumocystis* pneumonia—Los Angeles," *Morbidity and Mortality Weekly Report* 30(5 June 1981): 250-252; Alvin Friedman-Kien et al., "Kaposi's sarcoma and *Pneumocystis* pneumonia among homosexual men—New York City and California," *Morbidity and Mortality Weekly Report* 30(3 July 1981): 305-308.
3. Anthony S. Fauci, "The syndrome of Kaposi's sarcoma and opportunistic infections: an epidemiologically restricted disorder of immunoregulation," *Annals of Internal Medicine* 96(June 1982): 777-779.
4. Ibid., 779.
5. Dennis H. Osmond, Kimberly Page, James Wiley, Karen Garrett, Haynes W. Sheppard, Andrew R. Moss, Lewis Schrager, and Warren Winklestein, "Human immunodeficiency virus infection in homosexual/bisexual men, ages 18-29: the San Francisco Young Men's Health Study," *American Journal of Public Health* 84(1994): 1933-1937.
6. Jon Cohen, "AIDS research: the mood is uncertain," *Science* 260(28 May 1993): 1254-1265.
7. Anthony S. Fauci, "Multifactorial nature of HIV disease: implications for therapy," *Science* 262(14 November 1993): 1011-1018.
8. Phase I trials examine safety. Phase II trials are expanded tests of safety, as well as of dose determination, and enable researchers to look for early indications of efficacy. Phase III trials are focused on efficacy.
9. The classic criteria for a Phase III trial are general: that the vaccine is safe, immunogenic, and has shown potential for efficacy, or has shown early indications of efficacy.
10. Anthony S. Fauci, "Idiopathic CD4+ T-lymphocytopenia without HIV infection—no lights, no camera, just facts," *New England Journal of Medicine* 328(11 February 1993): 429-430.

Part II

AIDS and American Society

The National Commission on AIDS

June E. Osborn

In the fall of 1988, Congress passed PL-100-607, the first major piece of legislation intended to address the broad impact of the HIV/AIDS epidemic on American society; and as part of that initiative the United States National Commission on AIDS was established. A special effort was made to design the Commission in an unusual way, with appointments initiated equally by Democratic and Republican sponsors, and by both Congress and the President. It was the intent of the bill's authors that the resultant group of Commissioners would embody experience and/or expertise concerning the epidemic, and that it would be as independent and free of partisan politics as possible. During the four years from 1989 to 1993, the Commission served as an advisory body to both the legislative and executive branches of the federal government, commenting on policy issues, preparing and releasing reports to give guidance concerning AIDS-related matters, and—in preparation for these—holding hearings not only in Washington, D.C., but throughout the country. The National Commission on AIDS went out of existence when its authorization expired in September 1993.

On the day the Commission closed its doors, the *Washington Post* editorialized that "it ha[d] been extremely productive and often provocative . . . [and had] provided an important voice during this ordeal . . . ." Their concluding comment was that, ". . . by prodding, goading, criticizing and demanding action, [the National Commission on AIDS] has had an effect."[1] I am rather proud of that plaudit, for the *Post* is most often skeptical about Commissions, and indeed, the only power of such a group is that of persuasion, so having an effect was achieved against the odds.

Since its demise, the work of the Commission has been cited often, and it is becoming evident that its contribution to epidemic response will be durable. In the final analysis, the sixteen reports and numerous position statements made during those four years can serve as guideposts to the complex challenges and tasks that will be posed as the disastrous effects of AIDS and HIV press themselves on the society at large and call for thoughtful, coordinated strategies of public policy response. In this paper, I will recapitulate the thinking and events that led up to the Commission's inception, and will then try to summarize briefly its work and recommendations spanning four turbulent years of the AIDS epidemic in the United States.

The Need for Broad-Based Commissions to Deal with AIDS

First, I will explain the need for such a broad-based Commission. Expert advisory groups are a more standard mode for dealing with medically-based crises; but the predictably massive scale of the AIDS epidemic and its unusual impact on young adults in their most

productive years was noted by many analysts soon after identification of the human immunodeficiency virus (HIV). In 1986, the World Health Organization's Global Program on AIDS (GPA) included creation of a broadly constituted commission or advisory body as one of its criteria to be met by countries that wished the GPA to mediate in bilateral assistance efforts between donor countries and nations seeking help in meeting the anticipated epidemic impact.

In the United States, the Institute of Medicine (IOM)/National Academy of Sciences had created a study group early in 1986 that was given an unusually urgent charge to assess the epidemic and anticipate its future impact. In its resultant report, *Confronting AIDS*,[2] which was published in October of that year, the IOM group placed creation of such a broadly based expert Commission at the top of its list of recommendations.

The concept underlying this rather uniform international assessment was that the swath cut by a lethal disease of such magnitude would involve segments of society far beyond the reaches of biomedical science, health care professions, and public health. It could be anticipated, for instance, that issues would arise involving international travel, trade and commerce, justice, the military, education, labor, and religion; that government at all levels would be pressed to respond; and that affected communities would be diverse and should have input and involvement in the overall societal response.

The Reagan Response: The Presidential (Watkins) Commission

That strong recommendation from the National Academy of Sciences did not receive immediate attention. From the outset of the epidemic the Reagan Administration had maintained an almost perfectly consistent silence about the mounting numbers of people with AIDS. An important exception, of course, was the diligent and sometimes heroic efforts within the Department of Health and Human Services and particularly the U.S. Public Health Service; but even those efforts were sometimes made difficult by silence from the top.

Much of the initial momentum that led to research funding was generated or strongly abetted by Congress, and many individuals at all levels of society distinguished themselves with extraordinary individual effort. Nevertheless, President Ronald Reagan's response to the IOM report was sluggish and reluctant. It was not until the summer of 1987 that he appointed the Presidential Commission on the Human Immunodeficiency Virus Epidemic. When he did so, he chose a panel of fifteen individuals who knew little about AIDS at the outset; and he gave them only one year to study and report. He chose as their leader Dr. Eugene Mayberry, a distinguished physician from the Mayo Clinic who had been little involved in the social and policy issues surrounding AIDS and who knew very little about Washington and its ways. After three months of trying to manage the complex charge from a distance, he resigned his post. For the remaining nine months, the formidable charge was taken up by retired Admiral James Watkins of chairing the sharply divided group and of formulating a report about the status of the epidemic and the policy needs it would generate. In the re-grouping associated with Admiral Watkins's assumption of command, it is of special interest to note that Kristine Gebbie was also appointed to replace another Commissioner who had resigned. Her constructive role on that Presidential Commission has received much justifiable praise, as was noted by President Bill Clinton when he named her as AIDS Coordinator in June of 1993.

The accomplishments of what became known as the Watkins Commission were truly remarkable under such duress. The Commissioners undertook extensive hearings throughout the country, allowed for the airing of widely divergent views, and did indeed produce a

comprehensive, thoughtful report within the timeframe given them, after which they went out of existence.[3] If there was one drawback to their accomplishment, it was that the report embraced nearly 600 recommendations, making the task of tracking and following them a daunting one.

Creating an appearance of urgency, once the Presidential Commission Report was published in the summer of 1988, President Reagan then turned to an able professional, Dr. Donald Ian McDonald, to condense and prioritize the recommendations within the subsequent thirty days. Dr. McDonald was a pediatrician who had served as Acting Assistant Secretary for Health during much of the time the Presidential Commission was doing its work and he accepted the charge with commitment and enthusiasm. Sadly, when he completed his task, the entire enterprise fell dormant within the Administration.

Congress and PL-100-607

Thus began the history of the National Commission on AIDS. Members of Congress had watched the abortive process with concern, and as the summer of 1988 closed on Dr. McDonald's efforts, Congressman Roy Rowland (D-Ga), the only physician serving in Congress at the time, drafted legislation intended to create a quite different Commission that would be responsive to the recommendations of the IOM *Confronting AIDS* report.

To this end, the bill (and resultant law) stipulated that a National Commission on AIDS should be created, composed of individuals with experience and/or expertise pertinent to the AIDS epidemic; that the group should be constituted for a two-year term; and that its authorization could be renewed for a second two-year interval by simple request of the President. Its charge was spelled out in some detail, but could be summarized as a mandate to advise both branches of government, proactively and reactively, as needed, on a broad range of issues arising from the epidemic.

To assure a substantial degree of political independence, it further stipulated that five members of the Commission should be appointed by the Senate, five by the House of Representatives, and two by the President, making a total of twelve voting members. It should be noted that, with a Republican President and with Democrats in control of both houses of Congress, that translated into six Commissioners named by each political party, assuring at least a bipartisan—and hopefully a nonpartisan—context in which to work.

The Commissioners thus designated were to elect their own leadership from among their members. It was through that mechanism that I, as a Democratic Senate appointee, became chairwoman of the Commission, with Dr. David E. Rogers, University Professor of Medicine at Cornell Medical College, one of President George Bush's two appointees, as Vice-Chairman.

In addition to the voting members of the Commission, the law further stipulated that three Cabinet Secretaries should also serve as members ex officio—the Secretaries of Health and Human Services, Defense, and Veterans Affairs. The Chair was to seek and appoint an Executive Director, subject to approval of the Commission members. The first Executive Director was Ms. Maureen Byrnes, who had served in important staff roles for Senator Lowell Weicker and Senator Arlen Specter. She served with great diligence for the first two years, and when she stepped down in 1991 she was succeeded by Dr. Roy Widdus, whose background included Project Directorship of the IOM *Confronting AIDS* report and a major role in the World Health Organization's GPA.

Finally, the bill authorized sufficient funds to permit staffing, professional consultation, and resources for hearings, production of reports, and so forth.

The appointment process proceeded rather slowly and with some regrouping along the way. It was not until August of 1989 that the membership was complete. In addition to Dr. Rogers and me, the other commissioners appointed by the Senate were Professor Harlon Dalton of Yale Law School; Mr. Larry Kessler, Executive Director of the Massachusetts AIDS Action Committee; Ms. Eunice Diaz, who had worked extensively with the Latino/Hispanic community and who held an adjunct faculty appointment in the Department of Family Medicine at the University of Southern California; and Dr. Charles Konigsberg, then Health Director for the State of Kansas, who later assumed a similar position in the State of Delaware.

The House of Representatives appointed Ms. Diane Ahrens, County Commissioner of Ramsey County, Minnesota (in which St. Paul is located); Dr. Don C. Des Jarlais, from Beth Israel in New York City; Reverend K. Scott Allen of Dallas, Texas; Donald S. Goldman, Esq. of Livingston, New Jersey; and the Honorable J. Roy Rowland, (D-Ga), the physician who had, as I noted earlier, fathered the legislation that created the Commission in the first place.

Finally, in addition to Dr. Rogers, President Bush also appointed Ms. Belinda Mason, from rural Kentucky, who was then serving as President of the National Association of People with AIDS (NAPWA). That appointment was an exceptionally strong one and Ms. Mason's role as a member of the Commission is a topic worthy of its own detailed consideration. Sadly, she died in September 1991; and indeed her "slot" was the only one in which a vacancy occurred on the Commission during its four years of activity. Initially she was replaced by Earvin "Magic" Johnson, and when he stepped down in 1992, the President appointed Mary Fisher to fill the vacancy. These three Commissioners, in sequence, contributed invaluably in bringing the important voice of people living with HIV to all the Commission's deliberations.

The original intent to involve Cabinet Secretaries of three executive departments was not realized literally; however, all three were represented by surrogates at every meeting of the Commission, and some individuals participated with great consistency and became further components of the stability of Commission membership: notable among these were Irwin Pernick, Esq., from the Department of Veterans' Affairs, Dr. Michael Petersen from the Department of Defense, and Drs. James Allen and Valerie Setlow from the Department of Health and Human Services. Assistant Secretary for Health James O. Mason attended frequently and contributed significantly.

Thus the membership of the Commission was, with the one exception, entirely stable throughout its four years, and the kinds of expertise and experience brought to the table were both extensive and appropriate. The breadth of background made it what I usually referred to as a "citizens' commission," and with that feature it was almost ideally constituted to perform the public policy advisory role that had been intended. I will confess that I made a special effort not to veer into technical areas where expert committees or professionals were already deeply engaged—since under the best circumstances that would be a redundancy of effort and under the worst a kind of interference that seemed inappropriate. Instead, as we chose our path, we looked for issues that were cross-cutting or entirely unattended by existing responsible bodies.

The Four Years of the National Commission on AIDS

That background sets the stage for me to recount the work of the Commission—with one additional caveat of importance. The wisdom of Dr. David Rogers, and his long experience with advisory groups, was invaluable in many ways, but none more important than his early

and winning argument that we should express ourselves succinctly, simply, and with as few recommendations as possible if we were to engage the attention of policy makers and the public. The result was that we produced our first, brief report only two months into the life of the Commission, stating starkly and directly that the United States health care system was failing to deal with the exigencies of the AIDS epidemic.[4]

Since our first report was not, by law, required for another ten months, that captured press attention. In fact, the evening it appeared in December 1989, Jim Lehrer of the McNeil/Lehrer NewsHour asked me in a televised interview why we had issued a report so soon, to which I responded that it was not "so soon—in fact, it was terribly late." I think the atypical behavior of the Commission in that first non-standard report set the stage for our success—for without question, keeping issues of HIV and AIDS "on the screen" was one of the most important unwritten tasks we had at hand. From that point forward, the press corps at least kept an eye on us, and several hearings were deemed interesting enough to warrant full C-Span coverage as well as episodic interviews and the like. For that success much credit must go to Mr. Thomas Brandt, associate director of the Commission staff, who had also crafted the highly successful communications component of the earlier Presidential Commission's work.

From that first report we went to a series of additional statements, derived in large part from hearings and site visits around the country. Without going into exhaustive detail about these, it should be indicated that the Commissioners visited hospitals and hospices, homeless people and housing sites intended to alleviate the homelessness of people living with AIDS; we talked with addicted drug users and people in recovery; with people conducting legal and illegal needle exchange programs. At one time, as we attempted to appreciate the problems of AIDS in far-flung rural areas, we actually hopped across the huge state of Georgia in a C-130 air transport plane provided by the Georgia National Guard. When we addressed the problem of AIDS among Native Americans, we split into three groups so that we could visit fully fifteen nations in order to appreciate the diversity of that minority "group."

We heard from community based organizations, from a wide variety of ethnically based support groups, and from activists of all degrees of stridency. In that regard I am happy to note that we never had a single word of our proceedings drowned out or even interrupted; I believe it was because we clearly wanted to hear from and consider the input of everybody, and it greatly confirmed my belief in open process.

The reception of the Commission was remarkably cordial throughout the country, especially as time went on and our visibility increased. In a number of venues the governor of the state and/or the mayor of the host city greeted us and voiced appreciation and support, as did (always) the local AIDS groups. The last to join in were the medical professional groups, but even there things changed: it is noteworthy that, at our final set of hearings in Austin, we were welcomed at a breakfast-reception by the Texas Medical Society itself.

Often we were able to deal extensively with local media, and in a number of cities Thomas Brandt and I met with the editors or editorial boards of the major local newspapers, trying to establish greater depth of background about AIDS issues. The balance between local and national coverage was a difficult issue, especially since we could visit only a small fraction of the communities heavily impacted by AIDS. But in the places where we did manage to go, for a little while the effect on the community and the bolstering of AIDS-responsive organizations were regular parts of our accomplishments.

The method by which the Commission decided on recommendations and prepared its reports was not in itself remarkable; but the fact is that, with such a diverse group appoint-

ed through the political process, it is notable that we accomplished all our work through consensus. There was only one recommendation in the entire four years on which one Commissioner felt sufficiently strongly to wish to register a dissent; there were a number of other instances in which specific Commissioners voiced their unease, particularly since some held elected office, but were content simply to register their concerns without insisting on a vote. Even those issues were rare, and it is fair to say that virtually the entire body of the Commission's work represented strong consensus of the group.

The numerous reports of the Commission will remain available.[5] I cannot list all their recommendations in detail, but perhaps a summary of topics will serve to give an idea of the Commission's concerns. In addition to the health care report at the outset, we put out sequentially reports on: responsibilities at different levels of government; the need for leadership; clinical research; impending needs in the health care workforce; rural impact; HIV disease in correctional facilities; the twin epidemics of substance use and HIV; health care financing options; special issues of HIV/AIDS in Puerto Rico; the special importance of housing in community AIDS response; prevention of HIV transmission in health care settings; the challenge of HIV in the workplace; and special issues concerning adolescents.

Some of the reports deserve special mention. First, there were two comprehensive reports mandated by Congress in the authorizing legislation: one at the end of two years and one as we closed our doors after four years of work. The two-year report, entitled *America Living with AIDS* represented a rather exhaustive, good faith effort to put forward our best thoughts and recommendations—succinctly and usably—after two years of hard work.[6] During those two years we had traveled fairly extensively and had heard from over one thousand witnesses whom the excellent Commission staff had identified as specially qualified by virtue of experience or expertise—always with an awareness of the need to hear from affected communities and to make up, through witnesses, those gaps that existed in the representativeness of our membership as Commissioners.

Americans Living with AIDS was a success, I think. The report tackled the areas of prevention, care, financing of health care for people with HIV/AIDS, clinical research, and the role of government. In each section we constrained ourselves to a few recommendations; and in the executive summary, overview, and introduction we tried to maintain our tradition of using clear language of a sort that would make the report useful to future readers who were not specialized in particular technical backgrounds. A partial exception was the section on health care financing—there we felt that the issue was so pressing that we had to address it, but that expertise was clearly required to delineate viable strategies and options. For that special role we were fortunate to have Dr. Karen Davis and her colleagues from the Johns Hopkins University serve as consultants to provide expert consultation. The products of their work were incorporated, by the Commissioners, into recommendations; the work itself was so useful that we preserved it in the form of a separately published report.[7]

The second comprehensive report, entitled *AIDS: An Expanding Tragedy*, was released in the summer of 1993 as we began to close down,[8] and I will address it in my conclusion. But first, there are three of the topic-specific reports which I want to describe briefly. From the point of view of impact, I think the report entitled *The Twin Epidemics of Substance Abuse and HIV* was surely one of the most important, for it helped to reopen a dialogue that had shut down.[9] Important preventive interventions, particularly needle exchange, had been validated to impede the rapid spread of HIV that was associated with injection drug use; and yet in mistrustful communities already under extreme threat of their very survival from the drug epidemic, options such as needle exchange or even bleach instruction seemed to be offensive. Indeed, in the absence of provision of treatment for addiction, they seemed to be

"easy outs" for a majority society that wished the communities ill.

The National Commission on AIDS joined all previous advisory bodies in calling loudly and persistently for drug treatment; and we clearly identified needle exchange or bleach programs as stop gap strategies until the longer term goal of drug treatment capacity could be met. We were delighted that our report evoked supportive editorials in many major newspapers, and in its wake Chairman Charles Rangell reconvened the House Select Committee on Narcotics for a hearing, taking testimony from Dr. Des Jarlais and me as well as others, and then requested a General Accounting Office study that, in its outcome, further supported our recommendations. The issue is still very much alive, but I believe we played a role in reinitiating and moving the debate.

The report on *HIV Disease in Correctional Facilities* had a less direct effect but still seems to have played a salutory role.[10] I have been told that it is being used as a text in courses on corrections; and indeed it has helped to reopen discussion of the shameful state of health care in prisons and jails. Our "freshening effect" on that debate seems to have come from the report's focus on prison populations as a public health opportunity lost. The pulse of measurable reform is not yet palpable, but I do think we have helped to restart it.

That report leads to what I, personally, believe to have been the Commission's most unique contribution: the report entitled *The Challenge of HIV/AIDS in Communities of Color*.[11] As we wrote the earlier reports, we consciously deferred comment on the gross overrepresentation of people of color among intravenous drug users and prison populations, since we felt it would serve as a distraction to the main themes of those discussions. The tendency to try to marginalize, and therefore to trivialize, the HIV/AIDS epidemic was very striking among majority communities wherever we went, and especially so in the great center of the country, away from the coasts. To make strong points about prison health, but then to add that 85 percent of prisoners were people of color, seemed to be a strategy fraught with the peril of being ignored.

So instead we "held our fire," as it were, and refrained from pointed comments about ethnic and racial disproportion in those topic-specific reports. Then, under the remarkably able leadership of Commissioner Harlon Dalton, himself an African American man who had earlier written a provocative piece entitled "AIDS in Blackface" that had appeared in *Daedalus*,[12] we focussed our concerns in the *Communities of Color* report.

In it, we opened with a section that voiced general concern about racism and ethnic divisiveness in the United States and about the mounting disproportions of representation of HIV in African American and Latino communities, the special unrecognized threat to Native American and Asian/Pacific Islander groups, and we tackled some previously unaddressed ongoing issues threatening gay and lesbian populations. We sought special help, in other sections of the report, from consultants within each community to augment and refine the troubling considerations that had been raised in hearings that, by the time of the report, spanned over three years. The reason I am particularly proud of that report is because it contains important concerns and discussion that desperately needed to be given voice; and I cannot think of another group that was in a position to have done it just then.

To complete my survey I come to the Final Report. As we approached the end of four years' work, the Clinton Administration was in office, much more promising signals had been sent to the HIV-affected community, and we had in hand a rather large body of work and recommendations that had been relatively little heeded. After some discussion we concluded that our several topic-specific reports plus the two-year comprehensive report still held up well as guidelines to needed action; and that our goal—via the Final Report—was to ensure the accessibility of that earlier work and then to "shout" as loudly as possible on

our way out the door. To that end, the document entitled *AIDS: An Expanding Tragedy* included a very brief text, a list of principles to guide future AIDS policy, and only two final recommendations. The bulk of the document was an indexing of topics dealt with throughout the life of the Commission; a tabular chronicle of our meetings and work; a compilation of the recommendations made in each earlier report, and, very importantly, a list of the witnesses who had testified at each of our hearings. Since the latter constitute a previously hard-to-find human resource, the list may be one of the most durably useful sections of the report for future policy makers, for I think the Commission staff did a uniquely capable job of ferreting out the best of many kinds of people and expertise.

I will conclude with two parts of that report: first, its preface, written by David Rogers and me—to give a sense of our style and mood—and then the two final recommendations. The preface was:

> Composing a 'final report' on a massive, dynamic and unstable epidemic as it engulfs our nation and the world is like trying to take a snapshot of a tidal wave: its pace and scope defies capture. The enormous burden of grief and loss that AIDS will impose on our society has yet to be felt fully, and the work in care, prevention, and research must be not merely sustained but accelerated just to keep pace.
>
> The National Commission on AIDS has completed its four-year assignment to advise our government and our nation on issues and needs arising from the AIDS epidemic. We have listened to literally thousands of concerned Americans in dozens of hearings and site visits across the country, made recommendations on critical issues, and worked hard, with occasional success, for their adoption. However, our authorization expires in September 1993 and we will cease our contributions to that Herculean task. Thus, despite the enormity of the work remaining to be done, this report is truly final so far as our specifically mandated efforts are concerned.
>
> This is a short, sometimes angry report tinged with sadness and foreboding. It is short, because all of what we say here has been said many times before. It is sometimes angry because the carefully considered, widely heralded recommendations contained in our previous reports have been so consistently underfunded or ignored. It is sad because a potentially preventable disease continues to expand relentlessly and cause loss of life in young Americans on an unprecedented and unacceptable scale. The human immunodeficiency virus (HIV) has profoundly changed life on our planet. America has not done well in acknowledging this fact or in mobilizing its vast resources to address it appropriately. Many are suffering profoundly because of that failure, and America is poorer because of this neglect. We are apprehensive because the situation will worsen without immediate action. . . .[13]

Our two final recommendations in the report were simple and repetitive of earlier ones: (1) Leadership at all levels must speak out about AIDS to their constituencies; and (2) We must develop a clear, well-articulated national plan for confronting AIDS.[14]

It was a privilege for all of us involved in the National Commission on AIDS to be able to participate in this way in efforts to help with a great national and global tragedy. It was

pro bono work, superimposed on full-time jobs and lives complicated in a number of instances by illness and personal loss; but it was inspiring to learn to know the American people in their glorious diversity, and to appreciate more and more fully the exciting challenge of our declared goals as a democratic, pluralistic society.

I am not optimistic, in the usual superficial sense, about quick fixes or sudden conversions to the Commission's way of seeing things; but I am very hopeful, in the more profound sense, that we can find a way past this awful thicket of AIDS trouble, especially if we, as a people, can learn to listen to each other and to deal with matters of health care and illness with mutual dignity assured as a common currency. As of this writing I am unaware of plans to create a successor group, either as a Presidential or a congressionally mandated Commission; but the experience of the past several years persuades me that the international consensus noted at the outset of this discussion was valid and will only become more so. The scale and complexity of the AIDS epidemic will require coordinated response from segments of society far beyond the biomedical and public health communities, and a "citizens' committee" that is well informed and diligent can play a crucial role in national response.

Notes

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4. National Commission on AIDS, *Failure of U.S. Health Care System to Deal with the HIV Epidemic* (Washington, D.C.: National Commission on AIDS, 1989).
5. Reports can be requested from the Centers for Disease Control National AIDS Clearinghouse, Box 6033, Rockville, Maryland 20849-6003.
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9. National Commission on AIDS, *The Twin Epidemics of Substance Abuse and HIV: A Report* (Washington, D.C.: National Commission on AIDS, 1991).
10. National Commission on AIDS, *HIV Disease in Correctional Facilities* (Washington, D.C.: National Commission on AIDS, 1991).
11. National Commission on AIDS, *The Challenge of HIV/AIDS in Communities of Color* (Washington, D.C.: National Commission on AIDS, 1992).
12. Harlon Dalton, "AIDS in blackface," *Daedalus*, "Living With AIDS, Part II," 118(3) (Summer 1989): 205-227.
13. National Commission on AIDS, *AIDS: An Expanding Tragedy*, Preface, vii.
14. Ibid., 13.

The Implications of AIDS for the Development of Therapies and Vaccines: A Pharmaceutical Industry Perspective

R. Gordon Douglas, Jr.

A century ago, infectious diseases accounted for one-third of all deaths in the United States, and physicians were largely powerless in treating these afflictions. Tuberculosis, pneumonia, diarrhea and enteritis, bronchitis, and diphtheria were among the leading causes of death in 1900. With few exceptions, today these conditions are readily prevented or treated with widely available vaccines, antibiotics, and other medicines, most of which were introduced by the research-based pharmaceutical industry. For instance, pharmaceutical firm Merck & Co., Inc.'s tradition in vaccines dates back 100 years, to 1895, when the company introduced the first diphtheria antitoxin in the United States, and Merck was among the pioneers in producing penicillin and streptomycin during and after World War II. As a result, today's patients have come to expect that physicians can attack and cure just about any transmissible ailment they might contract. Smallpox, after all, was completely eradicated in 1977, and the Pan American Health Organization reported in September 1993 that in the past two years there had been no poliomyelitis cases at all in the Western hemisphere.[1] In this context of success and high expectations, the emergence and spread of AIDS is truly a troublesome turning point. According to the World Health Organization (WHO), more than seventeen million people worldwide are infected with HIV, and roughly four million have developed full-blown AIDS. The WHO estimates that as many as thirty to forty million cumulative cases of HIV infection could develop by the year 2000. As Allan Brandt has observed, "AIDS threatens our sense of medical security": the public expects the medical community to find answers for new diseases, and AIDS, unfortunately, is still lethal.[2]

Finding effective treatments for those infected with HIV is clearly one of the top priorities for biomedical research today, involving thousands of researchers in the basic and clinical sciences at academic, government, and industrial laboratories around the world, including Merck. Indeed, a 1994 survey by the Pharmaceutical Research and Manufacturers of America reports that 107 medicines and vaccines are in development by 81 different companies.[3] This essay discusses Merck & Co.'s efforts to develop new therapies and vaccines for AIDS, and places those efforts in the context of the pharmaceutical industry's overall approach to the problem. I begin with the critical success factors involved in the assault on AIDS, some of the difficulties to be faced in clinical research and regulatory review, and the challenges of distributing new therapies to the patients who need them around the world. I conclude with a brief overview of the Inter-Company Collaboration for AIDS Drug Development, an unprecedented consortium of fifteen leading pharmaceutical companies designed to help hasten the process of finding effective treatments.

First, let me note that Merck's objectives are to develop the most effective therapies and vaccines for AIDS in the most efficient manner possible, and get them licensed and delivered

as quickly as it can to patients whose lives depend on them. In the best of times, drug or vaccine discovery and development is a risky business. But because HIV is such an intricate virus and AIDS is such a complicated and deadly condition, this disease presents extraordinary challenges to the global medical community. Nonetheless, I am confident that successful treatments and preventives for AIDS will be found, but it will take cooperative efforts of the private and public sectors, and it will not be easy.

Despite the strength of commitment to treatment and prevention, resources *are* finite, and there are limitations on what industry can realistically do—or be expected to do. Government's role—and responsibility—in this search is to fund some of the basic scientific research that gives us a foundation for the development of new antivirals, immunostimulants, and vaccines. Government should also work with industry to overcome the hurdles inherent in bringing these to the marketplace. The pharmaceutical industry's role is to discover, develop, manufacture, and market new vaccines and therapies. Working together, government and industry need to overcome a number of major hurdles.

Critical Success Factors in the Assault on AIDS

There are four basic critical factors to consider in developing effective treatments and preventives for AIDS: technical feasibility; sustaining incentives for innovative research and development (R and D); overcoming difficulties in clinical research and regulatory review; and how to distribute the new therapies to people in need.

Technical Feasibility.

Available therapies so far have been hampered by toxicity and limited effectiveness. For example, patients on AZT face the threat of anemia; ddI patients can develop pancreatitis; and ddC patients sometimes experience peripheral neuropathy. An allied problem with current therapies, and many of those in early clinical trials, is the rapid onset of resistance. This has led to a strategy of trying to develop combination therapies. But HIV has proven to be remarkably adaptable, making it impervious to many of the weapons now available to fight it.

There are two key aspects to this adaptability. First, the virus mutates rapidly in the face of challenges from different antiviral agents. That property alone would not necessarily be a problem, if the mutant strains were not robust enough to survive and if they did not remain virulent. However, HIV's turnover time is so fast, its mutation rate is so high, and the number of progeny of each generation is significant enough that selection pressures quickly lead to the dominance of resistant strains of the virus. Add to that the relatively high virus titers in infected individuals, and a situation occurs in which HIV can respond to a therapeutic challenge with new strains resistant to the agent within a matter of weeks.

Just as important is the antigenic variation of HIV, which has major implications for vaccine research. Unlike other viruses, such as measles, mumps, and rubella (which do not mutate) or influenza viruses (which, while known for variable antigenicity, change slowly enough that an annual change in the vaccine is sufficient), HIV varies so extensively and unpredictably—both among a population and within an infected individual—that we have been unable to find a vaccine that can combat it effectively. And that assumes it is possible to define what constitutes effective immunity—which has not been done. What is more, successful therapeutic agents against AIDS will need to deal with these unpredictable properties of HIV without the drawbacks of toxicity. That has proven to be a tall order, despite dozens of research projects with various approaches in vaccines, or inhibitors of reverse transcriptase, HIV-1 protease, or the regulatory protein, Tat.[4]

Sustained Incentives for Innovative Research and Development.

The United States leads the world in drug discovery because our research system is an effective partnership between government, academe, and private industry and because the free market economy has provided an environment that supports sustained innovation. Government excels at basic research, both in its own laboratories and through funding of academic science. Industry—which also does basic research—excels at developmental research and manufacturing, the most costly and time-consuming phases of the process. Government scientists facilitate clinical studies, but they do not generally conduct or pay for the clinical research, process R and D, quality control, regulatory development work, and manufacturing investment required to bring new therapies to patients who need them. Vaccine development provides a good example of the complexity of the process and the institutional, economic, and social pressures involved.[5]

In 1983, there were eleven companies involved in the discovery, development, and manufacture of vaccines in the United States: now there are only four. Merck is one of only two United States-based firms still in the business, and only one other company manufactures vaccines in the United States. If claims that vaccine profit margins are excessive were true, one would expect to see a reverse trend. Instead, company after company decided to leave the industry. In the 1970s and early 1980s, the key reasons were low profitability and increased liability. The National Vaccine Injury Compensation Program, created by Congress in 1986 and implemented in 1988, provided a measure of stability on the liability front, and a few more pharmaceutical and biotechnology companies have entered the field since then, largely through mergers and strategic alliances designed to develop new pediatric combination vaccines.[6]

But more recently, the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), with its provisions for near-universal government purchase of vaccines for childhood immunization at discounted rates, provided cause for concern. Merck has consistently been a partner with federal and state governments and volunteer organizations in the effort to reduce barriers to immunization, and it shares the goal of assuring the availability of vaccines for children whose families cannot afford them. But as a result of the government's mandate to expand the state option to purchase discounted vaccines, there could be serious negative consequences for vaccine profitability and, consequently, for long-term investment in vaccine research. Why? To put the issue in perspective, it is important to note that there are only three sources for research and development funds in vaccines (or, for that matter, any new medical therapy):

1. With taxpayer dollars, the federal government funds roughly $250 million in basic and clinical research on vaccines, the majority at the National Institutes of Health, where vaccine research competes with other worthy causes ranging from breast cancer to schizophrenia. These health research dollars in turn compete with other priorities in the federal budget.[7]
2. Biotechnology companies (still generally small startup companies) fund roughly $100 million in vaccine research each year with equity capital from investors, but in recent months there has been a flight of billions of dollars of capital from the industry given the uncertainties of healthcare reform and the skittishness of investors looking for short-term gains.
3. The pharmaceutical industry (which also conducts research in biotechnology) funds at least $400 million per year in vaccine research from the returns on sales revenue, which

balance the discounted prices for public sector purchases and the prices available to children of insured and affluent families. If the traditional private vaccine market is eroded as a result of the expanded government vaccine purchase programs under OBRA '93 (by subsidizing distribution to families who can afford to purchase vaccines), Merck's ability to maintain its commitment to continued investment in the discovery and development of new vaccines—including those for AIDS—is in question.

The added stability on the liability issue provided by Congress in 1988 through the National Vaccine Injury Compensation Act has thus been offset by the troublesome threat of decreased revenues for vaccine developers from the Clinton Administration's original Vaccines for Children program. While Merck shares the goal of assuring the availability of vaccines to children whose families cannot afford them, the Administration's policy supporting universal purchase of vaccines at discounted rates for distribution by government agencies is problematic on several counts. For instance, the U.S. General Accounting Office has stated that vaccine costs are not an obstacle to childhood immunization, and that the costly Vaccines for Children program will not result in more children getting their shots. Indeed, it is clear that this initiative will *not* improve immunization rates—which depend crucially on the infrastructure for delivery and on effective communication with parents, not on the price of the vaccines—but it *will* have an impact on the profitability of vaccine manufacturers by eroding the returns on sales revenues, which balance the discounted prices for public sector purchases and the prices available to children of insured and affluent families. (This erosion would result from shifting the 50-50 public/private market balance to a private market of less than 20 percent.) This situation, in turn, will force developers to reconsider their long-term commitment to investment in the discovery and development of new vaccines (including AIDS vaccines) if adequate returns are neither predictable nor certain. This includes continued industry research on new and improved vaccines—including combination vaccines and heat-stable, oral delivery, and timed release forms—which public health officials agree is one certain way to address barriers to immunization. More than anything else, government should provide the stability to ensure a steady flow of research funding for the development of promising new vaccines.

Recent claims that the United States federal government itself funds and conducts the majority of basic research leading to the development of new vaccines are simply incorrect, in part because they grossly underestimate the research and development spending of the vaccine industry.[8] In fact, industry is the leading source of new funds for vaccine research and development and of new vaccines. Most of the current vaccines in use have come from the private sector; examples include vaccines to prevent measles, mumps, rubella, poliomyelitis, pneumococcal pneumonia, hepatitis B, hepatitis A, and *Haemophilus influenzae* type b meningitis. As already indicated, worldwide research spending for major vaccine companies is some $400 million, and Merck *alone* invested more than $100 million in vaccine research and development in 1992.[9] Vaccine research and production are delicate, time-consuming, and resource-intensive. The ability to maintain a flow of new capital and profits for re-investment in basic research and capital investment for manufacturing is critical to the development of new vaccines and other therapies. The threat of decreased revenues for vaccine products (a real possibility with the constraints of OBRA '93 and the Administration's policy of encouraging universal purchase) will inevitably mean a decline in private sector research and development investments in coming years and a slowdown in the discovery, development, and introduction of new life-saving vaccines.

Overcoming Difficulties in Clinical Research and Regulatory Review.

It is becoming increasingly clear that the road to a safe, effective, and successful AIDS vaccine is longer and more tortuous than we originally expected. Initially the scientific community had high expectations because it thought that basic virology and immunology would lead quickly to finding a simple component of HIV that would produce a vaccine. But this view has proven naive, and a moment's reflection from the viewpoint of vaccinology explains why: all effective vaccines involve the duplication of a naturally-occurring protective immune response to the infective organism. But with HIV, there is no evidence of this protective response among infected individuals, a factor that was not appreciated enough early on. Secondly, early efforts were focused on relatively simple proteins or glycoproteins, e.g., gp160, gp120, and so on. Most effective vaccines involve whole viruses or whole bacteria, except where pathogenesis is known to involve only a single virulence factor, e.g., tetanus, diphtheria, or *Haemophilus influenzae* type b. Moreover, HIV has evolved a unique capability of adapting to immune system responses. This aspect of AIDS is what makes the basic biological and clinical research so challenging.

But once a viable vaccine candidate does emerge, it will be absolutely essential to have a productive partnership between the public and private sectors. Early safety, tolerability, and efficacy studies of an HIV vaccine will take place primarily in the United States and Europe, but large-scale efficacy trials will depend on populations in developing nations. Mastering the logistics alone (not to mention the intricacies of study design and analysis) will require close industry and government cooperation. Merck has the expertise to design efficient, scientifically rigorous, and medically sound programs to achieve licensure. But the company will need to work closely with the National Institutes of Health, WHO, and other government laboratories on studies to evaluate vaccines in special populations, to test alternate dosing regimens or formulations, and to assess the impact of pre-existing disease conditions in patients receiving an HIV vaccine. Particularly important is the need to develop an international consensus on standards for demonstrating the safety, immunogenicity, and protective efficacy of new vaccines. Such standards will provide advance guidelines to developers on criteria for eventual approval and adoption of vaccines in development, and will thus encourage the risk-taking and investment needed to complete the costly clinical development phase for new vaccines.[10]

Distribution to People in Need.

Obviously it is not enough to have an effective therapy: ways must be found to deliver it to patients in need. Gross inefficiences exist in healthcare delivery systems for underserved populations, both in the United States and in the developing world. Without an infrastructure on which to build a distribution network, no amount of innovative resources, economic incentives, or technology transfer will overcome these barriers and ensure access to populations at risk of HIV infection. Equally important will be a mechanism to pay for the vaccines and other new therapies, particularly in countries in the developing world.

Policy makers cannot rely solely on industry to solve these problems; the following example illustrates the magnitude of the task. Since 1987, Merck has donated supplies of MECTIZAN (a human formulation of the antiparasitic ivermectin) to agencies and governments around the world to treat people infected with onchocerciasis, or "river blindness," a painful and disfiguring illness endemic to certain equatorial regions.[11] This donation program has been enormously successful, having treated more than eleven million affected individuals. But even after working with the WHO's Onchocerciasis Control Programme and a

variety of voluntary agencies, MECTIZAN has yet to reach all who need it, despite the geographical concentration of the disease in equatorial regions of Africa and Latin America. And even this solution is not possible with an AIDS vaccine, because the populations at risk are too large to support a similar program. The only existing mechanism industry generally has to subsidize the cost of vaccine sales and distribution in the developing world is the price differential between sales in the developed world and sales elsewhere. Political as well as financial considerations limit how large that differential can be. Thus the solution to finding efficient ways to ensure the availability of new vaccines to all those who need them around the world will necessarily involve complex considerations of technical feasibility, economic resources, public policy, and political will.

One novel response to this challenge is Merck's recent project to transfer the technology for manufacturing recombinant hepatitis B vaccine to China, where hepatitis B is a major public health problem affecting both children and adults. The magnitude of the challenge is daunting. There are 360 million children in China who are at risk. Some 150 million Chinese are carriers of hepatitis B, and thus at increased risk to develop primary liver cancer. Of the 20 million children born in China each year, one in ten acquires chronic hepatitis B from its mother. To combat the spread of hepatitis B, the Chinese government turned to Merck.

Under a 1989 agreement, Merck sold to the Chinese the know-how to produce the vaccine, and worked with Chinese engineers, quality control, and production people, first in the United States, then at China's National Vaccine and Serum Institute, to design and then construct a plant in Beijing to manufacture 20 million pediatric doses of hepatitis B vaccine annually. The Beijing plant opened in October 1993; a second manufacturing plant, opened at Shenzhen in June 1994, has a similar capacity. China has thus found a mechanism to tackle a severe health crisis and to protect the lives of its 360 million children by developing indigenous expertise and manufacturing capabilities. This case illustrates dramatically the need for public and private sector cooperation to meet these challenges around the world and to move forward quickly to provide society with important new drugs and vaccines to conquer not just AIDS, but also the many other devastating diseases of our time.

What Is Merck Doing About AIDS?

Having reviewed the critical factors that will govern our success in developing new drug therapies and vaccines for AIDS, I want to turn to what is being done at Merck. Merck has made a major commitment to AIDS research for nearly a decade: in fact, it is one of the largest research programs in the Company's history.[12] The targets being investigated include the development of active preventive vaccines, antiretroviral drugs, passive immunoprophylaxis, and agents to prevent and treat opportunistic infections. Several drug candidates have entered clinical trials to date. But the route to a successful therapy has not been easy. For a sense of just how complex and risky drug development is, let me describe in some detail Merck's decision in 1993 to terminate development of the pyridinone non-nucleoside reverse transcriptase inhibitor, L-697,661.

Merck researchers had high hopes for this promising class of compounds when clinical development began in the fall of 1990. Preliminary clinical trials of four reverse transcriptase inhibitors were conducted and, based on clinical and preclinical data, L-661 was chosen for further development. Monotherapy trials began in December 1990. In anticipation of the development of resistance, the company began combination trials in the summer of 1991 in Germany. Clinical proof of the development of resistance to the monotherapy came

in less than twelve months, but combination trials continued for a full year and a half, into 1993. The hope was that by increasing the dosage and by combining L-661 with AZT (which inhibits reverse transcriptase through a different mechanism), the resistance problem seen with L-661 alone could be slowed down or prevented. While L-661 was safe and well-tolerated at the higher dosage—and did show significant dose-related activity against HIV-1—resistance still broke out rapidly and could not be suppressed. Moreover, this resistance problem made it likely that L-661 would not enhance AZT therapy; that is, the combination of the two was no better at sustained viral suppression than AZT alone.[13]

On the basis of these disappointing results, Merck decided that it should not hold out false hope to patients about L-661. Accordingly, in early September it decided to stop development of this compound. As HIV mutated rapidly against the drug challenge, the early promise of L-661 as a possible combination therapy with AZT was dashed. As is so often the case in pharmaceutical research and development, the basic and clinical research failed to lead to the discovery of a life-saving compound. Simultaneously, Merck had invested millions of dollars on a risk basis for parallel development of chemical processes to manufacture enough drug in the event of expanded trials. In the process, Merck researchers did gain valuable knowledge about the molecular biology of HIV (how specific strains of the virus developed resistance), and about the bioavailability and pharmacokinetics of L-661 (and, by extension, this class of compounds). But after years of research effort and millions of dollars invested, in a certain sense Merck was "back to square one."

Merck is continuing its efforts to discover and develop inhibitors that act against other enzymes of HIV. One of those targets is the enzyme HIV protease. Merck research on this enzyme began in 1985.[14] Early structure determinations were used to develop models for protease inhibitors that would work effectively in vitro and, it is hoped, in vivo. Five years of dedicated, difficult research led to a product candidate, but it failed in animal safety assessment early in 1990. It took three more years before another suitable product candidate was found, and clinical trials of the HIV-1 protease inhibitor, L-735,524 began in February 1993. The goal was to assess safety and tolerability and to make a preliminary assessment of L-524's antiviral activity. The early results provided evidence that L-524 was generally safe and well-tolerated (although there was some concern about elevated liver enzymes in some of the patients in the earliest trials). A pilot antiviral activity study begun in June 1993 at the University of Alabama in Birmingham and at Thomas Jefferson Hospital in Philadelphia, Pennsylvania, showed sufficient evidence of antiviral effect to proceed with the clinical development program.

Accordingly, a clinical trial was begun in October 1993 to test the antiviral effects of L-524 monotherapy (at 200 mg every six hours and 400 mg every six hours) in 60 HIV-seropositive, p24-antigenemic patients with CD4 counts below 500 cells/mm^3. Another small study was initiated to investigate the safety, tolerability, and biological activity of L-524 at 600 mg every eight hours. These studies showed encouraging signs that L-524 has a significant antiviral effect, measured by decreases in p-24 antigen and plasma viral RNA. Patients on L-524 also exhibited improvements in CD4 counts, weight, and hematological parameters. But after a number of weeks of treatment with L-524, the level of viral RNA in some patients began to rebound, and eventually returned to near-baseline levels; at the same time, the associated rise in CD4 counts also leveled and returned, in some cases, to near-baseline levels. This pattern could indicate the emergence of viral resistance.

The immediate response was to halt plans to expand the clinical program rapidly and to explore the causes of the viral rebound more fully. Merck's clinical scientists increased the dose of L-524 to 600 mg every six hours for all patients in the trial that began in

October, since in their judgment (and in consultation with outside investigators) this increased dose would be generally well tolerated by most patients and might increase the antiviral effect. Merck also began small clinical studies to test the safety, tolerability, and antiviral activity of L-524 in combination with AZT (in AZT-naive patients with CD4 counts less than 500) and of L-524 together with AZT and ddI (also in AZT-naive and ddI-naive patients with CD4 counts below 500). An additional 60-patient study (involving individuals with CD4 counts between 150 and 500 cells/$mm^{3)}$ is also being conducted to optimize the dose of L-524.[15]

It will not be known until early in 1995 whether the higher dose of L-524 or of L-524 combined with AZT and ddI is successful in overcoming viral resistance. As yet, the number of patients studied remains small and Merck researchers are gaining clinical data daily, keenly aware that HIV is a wily opponent, and that it is still early in the game. While the world anxiously awaits, progress has been slower than Merck hoped, and it has looked for other ways to speed up the development process.

The Inter-Company Collaboration for AIDS Drug Development

The innovative solution to this concern was the Inter-Company Collaboration for AIDS Drug Development, a virtually unprecedented consortium of fifteen leading pharmaceutical companies that have made a commitment to pool their efforts in order to identify the most effective AIDS therapies in the shortest possible time, and to deliver them to the patients whose lives depend on the success of their efforts. The Inter-Company Collaboration was announced in April 1993, with the specific goal of working together to facilitate early human effectiveness trials of combination drug therapies to fight AIDS and HIV infection. The objective is to expedite comparative studies of different investigational compounds—by sharing scientific information and drug supplies, and by collaborating on certain aspects of drug development such as assay standardization.[16]

The movement to create the Inter-Company Collaboration was led by Dr. P. Roy Vagelos (then Merck Chairman) and by Dr. Edward M. Scolnick, President of the Merck Research Laboratories. Dr. Vagelos and Dr. Scolnick, along with other research leaders and scientists, realized that, because of its unique adaptability, HIV was likely to develop resistance to every antiviral compound tested against it. At the same time, more and more compounds were becoming available for possible use in combination therapies that might mitigate the resistance problem. Discussions among leading companies took place for more than a year before the formation of the Inter-Company Collaboration to design a structure that would maintain competitiveness—to foster continued innovation—while catalyzing the sharing of data and compounds at an early stage in clinical development, where it might make a difference in the daunting odds against success. The Collaboration is not a "Manhattan Project" for AIDS: it is not a public sector initiative, nor are the scientific processes of HIV infection as well understood as nuclear fission was when J. Robert Oppenheimer and General Leslie Groves began their work during World War II. But the Collaboration's ambitious focus is appropriate for the current state of knowledge, and together, perhaps the companies can speed the development of effective AIDS therapies.

To date, the Collaboration's participants include: AB Astra, Aji Pharma USA, Boehringer Ingelheim, Bristol-Myers Squibb, Burroughs Wellcome, DuPont Merck, Glaxo, Hoechst AG, Hoffmann-La Roche, Merck, Pfizer, Miles (on behalf of its German parent company, Bayer), Sigma-Tau, SmithKline Beecham, and Syntex. All pharmaceutical companies actively involved in HIV antiviral development are eligible to join the Collaboration, and researchers

from universities and government, as well as representatives from the HIV community, are being consulted and kept informed on a regular basis. In addition, Dr. Scolnick and Dr. Stephen Carter (Bristol-Myers Squibb) from the Inter-Company Collaboration have been appointed to the National Task Force on AIDS Drug Development (chaired by Dr. Philip R. Lee, Assistant Secretary for Health of the U.S. Department of Health and Human Services).

The Collaboration meets periodically, and the exchange of basic scientific data on prospective antiviral agents is well underway, along with discussions on standardizing assay methodology and creating databases for antiviral resistance. One of the most exciting results of the Collaboration's first year of activity—a consensus protocol for the rapid evaluation of triple-drug combinations for the treatment of AIDS—was announced at the inaugural meeting of the National Task Force on AIDS Drug Development in April 1994, by Dr. Jürgen Drews of Hoffmann-La Roche, the Chair of the Collaboration's Scientific Panel.

The consensus protocol, developed by the Collaboration's Clinical Trial Subcommittee (led by Dr. David Barry of Burroughs Wellcome), uses a continuous cohort variable regimen modeled after a strategy that has led successfully in the past to treatments for leprosy, tuberculosis, and certain cancers. The selection of the triple combinations to be evaluated under the master protocol will be based on available clinical data generated by Collaboration members and scientific evidence of additive or synergistic effects of the combinations in cell culture, as determined by a standard laboratory protocol also developed by the Collaboration.[17]

The overall objective of the protocol is to identify those triple combinations of HIV antivirals that can produce significant decreases in plasma viral RNA and sustained increases in CD4 counts. Studies conducted under the master protocol are only *pilot* studies to identify truly effective triple combinations of HIV antiviral compounds. Additional studies will then be done to evaluate further the long-term safety and clinical benefit of triple combinations that look promising under this master protocol. The first combinations planned by the Collaboration will test various combinations of AZT, ddI, ddC, 3TC, saquinavir, and nevirapine. The master protocol has been reviewed by the U.S. Food and Drug Administration, and the Collaboration's Clinical Trial Subcommittee has revised the protocol, selected a clinical research organization to manage the project, and is preparing to implement the trials early in 1995.

Collaboration might seem antithetical in such a competitive industry environment as the pharmaceutical industry. But as George W. Merck observed in 1950, "Medicine is for the people. It is not for the profits...."[18] The critical need for effective AIDS therapies means that the best collective effort must be made to surmount the problems faced. By pooling knowledge about the available drug candidates, and approaching cooperative clinical trials of these agents in combination, members of the Collaboration are confident that they can develop new AIDS therapies more rapidly, thus benefiting the patients who need them and strengthening their own research efforts for new generations of therapy.

Conclusion

The Inter-Company Collaboration for AIDS Drug Development is the most recent innovation on the AIDS research front. It offers the best hope to optimize the chance of discovery and development of medicines and to expand and expedite access to new AIDS drugs that work against this elusive enemy. But I do not want to minimize the inherent risks or the uncertainty of our efforts. For the Collaboration to succeed with an effective AIDS drug, establishing technical feasibility is not enough. In addition, public and private sector coop-

eration is needed to ensure that the regulatory review process is quick and that delivery mechanisms do not impede the ability to reach patients in need. Most important, a climate that encourages investment in innovation must be preserved. That investment is the strongest guarantee that biomedical research will be able to stop the AIDS epidemic and restore our "sense of medical security."

Notes

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3. Pharmaceutical Research and Manufacturers of America, *New Medicines in Development for AIDS*, 1994 Survey (Washington, D.C.: Pharmaceutical Research and Manufacturers of America, November 1994).
4. The literature on the complex biology of HIV and the state-of-the-art in AIDS drug therapies and vaccine development is voluminous and growing rapidly. For recent reviews of HIV pathogenesis, see Anthony S. Fauci, "Multifactorial nature of Human Immunodeficiency Virus disease: implications for therapy," *Science* 262(12 November 1993): 1011-1018; and Robin A. Weiss, "How does HIV cause AIDS?" *Science* 260(28 May 1993): 1273-1279. On available drug therapies and research, see R. Gordon Douglas, Jr., "Antiviral Agents," in A. G. Gilman et al., eds., Goodman and Gilman's *The Pharmacological Basis of Therapeutics*, 8th edition (New York: Pergamon Press, 1990), 1182-1201; E. Sandström and B. Öberg, "Antiviral therapy in Human Immunodeficiency Virus infections—current status," *Drugs* 45(April 1993): 488-508, and (May 1993): 637-653; Margaret I. Johnston and Daniel F. Hoth, "Present status and future prospects for HIV therapies," *Science* 260(28 May 1993): 1286-1293; and Martin S. Hirsch and Richard T. D'Aquila, "Therapy for Human Immunodeficiency Virus infection," *New England Journal of Medicine* 328(10 June 1993): 1686-1695.

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7. Mitchell, Philipose, and Sanford, eds., *The Children's Vaccine Initiative: Achieving the Vision* (note 6), Table 3-5, 55.
8. Ibid., pp. 54, 82, 85-86 (Table 4-10). This Institute of Medicine study also underestimates the research intensity of the vaccine industry, as noted below.
9. Global sales of vaccines in 1993 were roughly $2 billion, and vaccine developers spend about 20 percent of sales on research and development. This yields a total of $400 million for the industry's investment in research and development. Company estimates.
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11. Erik Eckholm, "River blindness: conquering an ancient scourge," *New York Times Magazine*, 8 January 1989; William C. Campbell, "Ivermectin as an antiparasitic agent for use in humans," *Annual Reviews of Microbiology* 45(1991): 445-474.
12. A recent study of Institute for Scientific Information data on AIDS research between 1988 and 1992 showed that Merck was one of the three industrial laboratories among the ten leading programs in the field, as measured by citation impact: Phyllida Brown, "Has the AIDS research epidemic spread too far?" *New Scientist* 138(15 May 1993): 12-15; reprinted in *Current Contents* No. 27 (5 July 1993): 5-11; Figure 5 (on p. 11 of Brown's article) lists the following ten institutions as leaders in citations per AIDS research paper published between 1988 and 1992: Genentech, Dana Farber Cancer Institute, Georgetown University, Duke University, National Institute of Allergy and Infectious Diseases, Institute of Cancer Research, Massachusetts General Hospital, Abbott Laboratories, Merck Research Laboratories [actually listed as "Merck Sharp & Dohme"], and the National Institute of Dental Research. See also "AIDS research: which institutions are most productive and influential?" *The Scientist* (18 October 1993): 14, 17.

13. Michael S. Saag, Emilio A. Emini et al., "A short-term clinical evaluation of L-697,661, a non-nucleoside inhibitor of HIV-1 reverse transcriptase," *New England Journal of Medicine* 329 (7 October 1993): 1065-1072.
14. Joel R. Huff, "HIV protease: a novel chemotherapeutic target for AIDS," *Journal of Medicinal Chemistry* 34(August 1991): 2305-2314.
15. See J. P. Vacca et al., "L-735,524: an orally bioavailable Human Immunodeficiency Virus type 1 protease inhibitor," *Proceedings of the National Academy of Sciences* 91(April 1994): 4096-4100; Henry E. Chang, "Progress and prospects in protease inhibitor research," *Journal of the Physicians Association for AIDS Care* 1(July 1994): 8-15, esp. 12-13; and Bruce D. Dorsey et al., "L-735,524: the design of a potent and orally bioavailable HIV protease inhibitor," *Journal of Medicinal Chemistry* 37(14 October 1994): 3443-3451.
16. For an early report, see Jon Cohen, "Drug companies join forces in search for AIDS therapy," *Science* 260(23 April 1993): 482.
17. See David W. Barry and the Clinical Trial Subcommittee of the Inter-Company Collaboration for AIDS Drug Development, "A master protocol to evaluate the safety and efficacy of triple combination antiretroviral therapy for HIV infection," *BETA: Bulletin of Experimental Therapy for AIDS* (June 1994): 46-48; and Barry, "Triple combinations and future research directions," *Journal of the Physicians Association for AIDS Care* 1(September 1994): 28-31.
18. George Merck articulated this philosophy, which continues to guide Merck people, in a 1950 speech to the Medical College of Virginia: "We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear." See Jeffrey L. Sturchio, ed., *Values and Visions: A Merck Century* (Rahway, New Jersey: Merck & Co., Inc., 1991), 34.

AIDS and Minority Health

Mark Smith

In my paper I propose to tackle four issues. First, I will offer some personal reflections about my own career trajectory and how it relates to the stages of the AIDS epidemic; second, I will review facts about AIDS and minorities, some of which are widely known, some of which are perhaps known but have been forgotten; third, I will briefly enumerate the five issues that I think have characterized the minority response to AIDS; and, last, discuss the challenge of HIV prevention, which I think is the principal special challenge facing minority communities today.

Personal Reflections

In 1983 I was an intern on the inpatient Medical Service at San Francisco General Hospital. James Curran indicates in his paper in this volume that one way the AIDS epidemic was recognized was the fact that there was a dramatic increase in the requests to the Centers for Disease Control (CDC) for pentamidine isothionate to treat cases of Kaposi's sarcoma. When I was an intern, part of my job was to send a medical student to the airport to pick up a shipment of pentamidine from the CDC when we had a patient who had not benefited from treatment with Septra, a synthetic antibacterial drug.

Also when I was an intern, we used to go to the residents' report in the hospital in the morning and speculate about what "it" [the new disease] was. There was, of course, speculation going on at much loftier levels: at the CDC, the Public Health Service, and in Paris. But we young physicians were sitting around with a cup of bad coffee at San Francisco General Hospital asking, "What do you think this disease is? Is the cause a virus? Nitrites? What is this?"

Within a month of becoming a house officer at San Francisco General Hospital, I knew more about AIDS clinically than 99 percent of the physicians in the world. Interestingly, a number of us who were part of that cohort of residents at the University of California San Francisco have gone on to play important roles in dealing with the AIDS epidemic and have made major contributions to the understanding of AIDS.

For many of us confronting this disease was not something that we chose. I did not choose my residency because I wanted to be an "AIDS expert." What did we know about AIDS in 1983? My becoming knowledgeable about AIDS was a combination of being in the "right" place at the right time, and of who I was—what my previous life's history had prepared me to do in response to this epidemic.

In many cases, those of us who were in training when the AIDS epidemic started came to know a substantial amount about AIDS, and so we were asked to do more; the more we were asked to do, the more we became known for our expertise, and so on. We looked up

ten years later and found that we had a career that had been dominated by AIDS, perhaps without our ever deciding to work in this area.

In addition, being a good union man, I was a leader of the house staff union, the San Francisco Intern and Residents' Association, at San Francisco General and therefore I served on the hospital's Executive Committee. I thus was exposed early to the policy implications of the AIDS epidemic, which probably affected San Francisco General Hospital more than any other institution in the world, because of the way the epidemic developed.

Because of these experiences two years later when I was in Philadelphia and staff at the Pew Charitable Trust wanted to put together a Philadelphia AIDS Commission, a number of different people from the AIDS advocacy community, the clinical community, and the public health community all gave them my name. After all, how many people were there then who knew very much about AIDS? This interest by the Pew Charitable Trust led to a two-year project (1987-1988) in which the Philadelphia AIDS Commission examined the impact of the epidemic on every aspect of life in Philadelphia and the region—the arts, the health care system, the media, and so on. The project served as a model for a number of other examinations in other places.

Between 1986 and 1988 many of us who had been working on AIDS for a period of time were still generalists. I remember starting one day by having breakfast with a group of newspaper reporters trying to interpret the latest AIDS story; then talking to police officers who would be training their colleagues about AIDS, and getting questions about how long the virus would last on a counter (I knew little about virology, but I was the only person available so I answered the questions to the best of my ability); next addressing a group of teachers about whether or not AIDS could be transmitted by mosquitoes; and then, in the evening, attending grand rounds at a community hospital to talk about management of *Pneumocystis carinii* pneumonia.

It has to be understood that I am not an expert in HIV prevention. I am certainly not a virologist. But in those days if you were working on AIDS, people would expect you to do almost everything. There was tremendous interest in the disease and little expertise available. Many of the normal channels of professional development, certification, and specialization had not come into play.

This also applies to the history of the International AIDS Conferences. The Conferences were started in 1985 because all of the people who were investigating AIDS—a few epidemiologists, a few virologists, a couple of cell biologists, and a few clinicians—needed to know what the others knew. This was before there were whole journals devoted to AIDS or whole academic divisions working on AIDS. These days, of course, an academic's department chair does not care about whether a person gives a presentation at the International AIDS Conference; he or she cares about the person presenting at the microbiology meetings, or the gene splicing meetings, or whatever meeting it is that basic scientists go to. But in the mid-1980s many people did a little of everything.

The late 1980s were a period of great optimism about treatments for AIDS. There were increasing numbers of drug trials and high hopes for them. Therapeutics became more complex, and there were more options to offer patients.

In 1989 I moved to the Johns Hopkins Medical School in Baltimore to run its AIDS Clinic. After two years, in part for personal reasons but in part because of my desire for new challenges, I moved to the Kaiser Family Foundation in California, which now, among other things, funds many HIV policy projects. This is because it has become clear that the roads to treatments and vaccines will be much longer than we once thought or hoped, and that policies for the prevention of AIDS and treatment, particularly in the

context of health care reform, are the issues of the day.

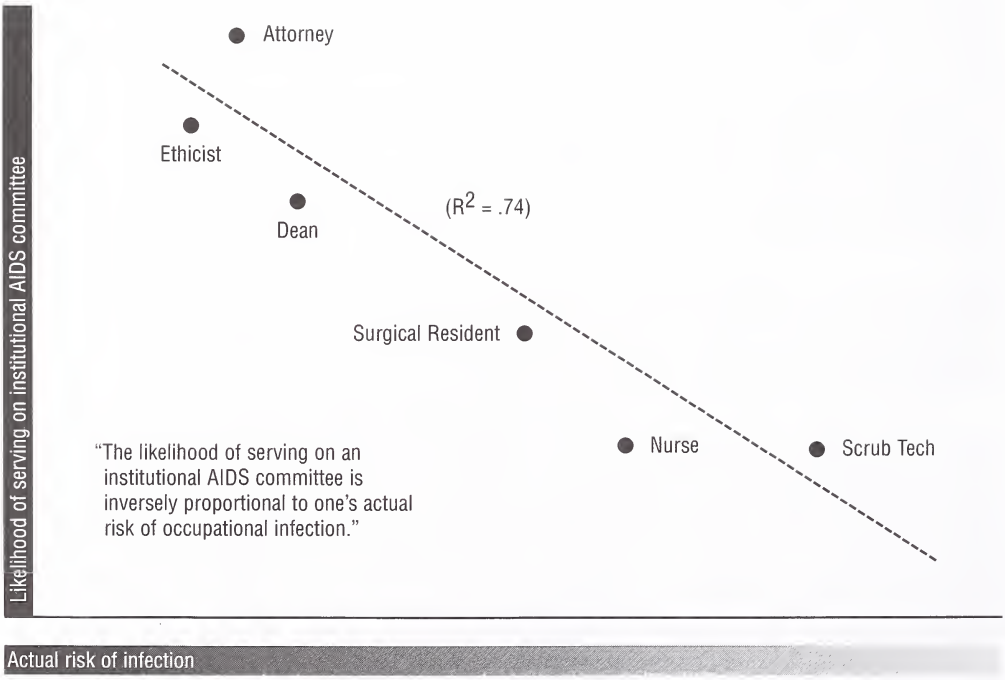
I do not know much about the laboratory, and I am not a full-time clinician, so I am unlikely ever to have a syndrome named after me. But there are two laws that I have discerned while working on AIDS that I think are worth noting. I have named them—for obvious reasons—Smith's Laws I and II.

Smith's Law I is as follows: "The likelihood of one's serving on an AIDS committee in a clinical institution is inversely proportional to one's *actual risk of getting infected.*" This is one of the few statistics that I will cite. The regression coefficient for this is 0.74 (Figure 1). This is relevant for people of color—aside from being a general observation—because it is the scrub nurses, surgical technicians, and phlebotomists who are more at risk for AIDS and who are much more likely to be people of color. The deans, the attorneys, and the ethicists, in my experience, are not likely to be people of color.

Smith's Law II is: "The amount of media attention and law-maker debate devoted to an HIV policy issue is inversely proportional to the capacity of that policy *actually to increase or decrease HIV transmission*" (Figure 2). We can look at the intensity of the debate over HIV-infected health care workers, immigrants, prisoners, needle exchange, versus the relative silence about drug treatment or sex education as a reflection of the truth of this law in practice.

I want to describe the kind of coalitions that developed over the years of the epidemic, and their evolution and disintegration. In looking back to the early days, who was it who investigated AIDS? It was a coalition of the few people in a number of fields who were interested in taking an active role with regard to this disease—public health officials, the gay

Figure 1. Smith's Law I



community, some minority activists, and clinician/researchers. The first researchers were all clinicians, because patients with Kaposi's sarcoma or with *Pneumocystis* pneumonia went to them. There were a few other people—clergymen, academics and so on—who were always interested in AIDS patients, and involved and active in their care.

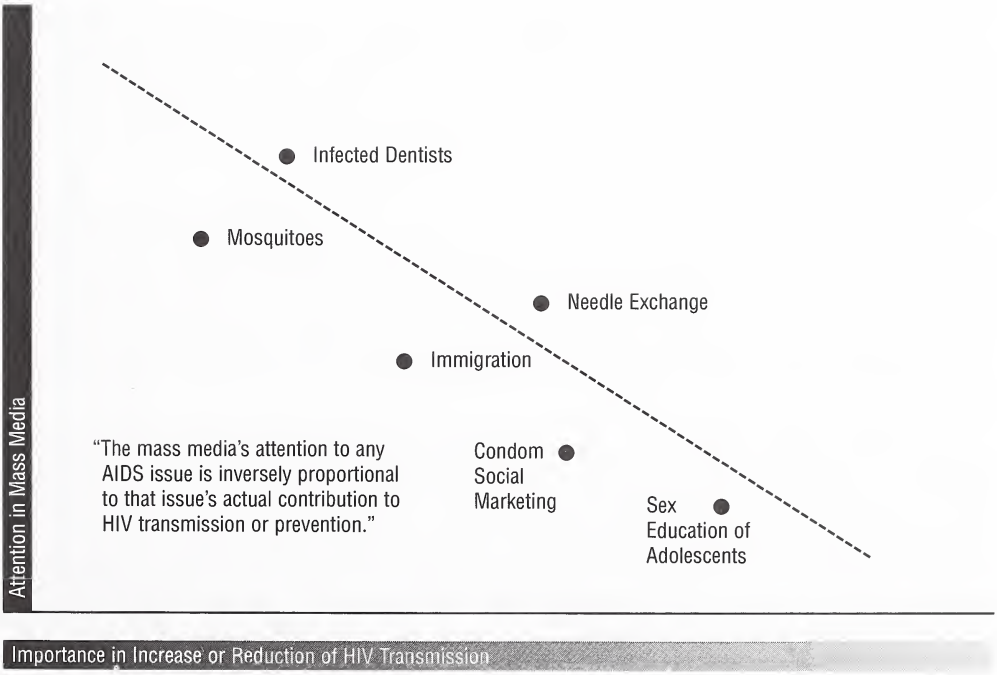
In my experience, what happened first was that clinicians and researchers began to differentiate themselves into two different groups. This was particularly true as patients with and without insurance began to show up.

The next development was that public health officials, who early in the course of the epidemic had presented a united front on issues such as testing, confidentiality, and name reporting, began to disagree; one began to see arguments, controversy, and demonstrations at AIDS conferences over particular states in the United States that had particular policies versus those that did not.

Next, the gay community went in two directions that, for the sake of simplification, I will characterize as: 1) the Gay Men's Health Crisis: a volunteer, caring, bring-people-meals, be-concerned-about-individuals direction; versus 2) ACT-UP—a throw-blood-at-the-NIH-and-demand-more-money-for-treatment-and-change-the-research-agenda direction. These directions are *not* mutually exclusive, of course, but Larry Kramer and other spokesmen for gays have talked about the development of these two different approaches in the gay activist community which has always, to its everlasting credit, been in the forefront of advocacy and political activism on HIV.

Then, of course, the minority community began to break up into its different component parts. These days, it seems that every minority group affected by HIV needs its own orga-

Figure 2. Smith's Law II



nization: with its own executive director, its own office, its own FAX machine, and its own overhead; and furthermore, that within each minority community each sexual preference also needs its own organization. "The Latino (or black, or Indian) organization over here cares only about gay people and we need a separate one for bisexual Latinos (or blacks, or Indians)," and so on. As money began to flow, one began to see more and more fights over the division of the money amongst different minority groups.

Lastly, there was the development of a very strong advocacy group composed of people with AIDS, who were members of gay *and* minority communities, and of those who were neither, with some overlap among all of these different groups. This advocacy group has increasingly been the engine for a large part of the much-needed activism that continues to go on relating to the epidemic.

AIDS and Minorities

It should be noted that from the very early days of the epidemic there was evidence that it was not just gay men that had AIDS. From the first reports about cases in New York, there were definitely some individuals who were involved in drug use and who, by all accounts, were not gay. While Gay Related Immune Disorder, "GRID," was one of the proposed names for the disease, it was clear that part of the public and political outlook on the epidemic was not only that gay men had the disease, but also that it hit minorities, and which minorities it hit.

AIDS disproportionately affects blacks and Hispanics in the United States population. The percentage of AIDS cases in blacks or Hispanics is about double the percentage of blacks or Hispanics in the United States population.[1] AIDS is already the leading cause of death among blacks and Hispanic men aged 25 to 44.[2] Also it is among blacks and Hispanics that much of the new infection is occurring. That infection is a slow, indolent, smoldering infection. This much is widely known.

The second fact, perhaps not so widely known, is that there has been, and continues to be, a strong connection between homosexuality/bisexuality and AIDS in communities of color. Among the 70,000 black men with AIDS in the United States, 43 percent have sex with other men as their probable route of transmission, 35 percent have intravenous drug use, and 7 percent have both. Six percent have no known source of infection.[3] So a majority of the black men with AIDS are men who have sex with other men.

The same holds true for Hispanics. Of the roughly 40,000 Hispanic men in the United States with AIDS, 46 percent are men who have had sex with other men, 38 percent are intravenous drug users, and 6 percent are both; so again, at least 52 percent of the Hispanic men with AIDS got it from homosexual or bisexual exposure.[4] An important undercurrent of this epidemic has been the racial stereotyping of "gay = white" and "minority = drug-user." This is not true, but the stereotype has played a large part in the public policy debates on AIDS.

"Minorities" are not all alike. I am careful to refer specifically to blacks and Hispanics. In terms of minority groups with HIV, Asian-Americans are underrepresented with respect to their numbers in the United States population. Native-Americans are also probably underrepresented. It is important then not to lump minorities together, as if they are all one group. "Minorities" are, of course, alike in that they are not exclusively Caucasian—that is the social definition of a "minority" in the United States. But behaviorally, with regard to the AIDS epidemic, they are not all alike.

Even within one of these minority groups, there are profound social and cultural

differences. For instance, the group "Hispanic" includes Mexican-American, Cuban-American, Central American, Puerto Rican, and others. A CDC study published two years ago demonstrated that intravenous drug use was implicated in 61 percent of the Hispanic men with AIDS from Puerto Rico, but in only 27 percent of the Hispanic men with AIDS from the Dominican Republic, and in less than 10 percent of the Hispanic men with AIDS from other places.[5] Further, consider the designation "Puerto Rican." The nine-year cumulative age-adjusted acquired immune deficiency syndrome mortality rate for males was found to be five times higher among Puerto Rican-born New York residents who are "Puerto Rican" than among New York-born New York residents who are "Puerto Rican."[6] A reductionist approach to these very complex social categories obscures important facts.

Casual generalizations about people who are "Hispanic" or "Puerto Rican," hide rich, complex, sometimes baffling, social texture: they obscure information about the way people actually live and behave that provides important clues as to how this epidemic has spread and how its spread might be stopped. Consider the following case study. A 64-year-old patient who was admitted to the Medical Service at San Francisco General Hospital—I will call him Mr. Ortega—presented with a baffling pneumonia, which did not get better when it was treated with cefuroxime or erythromycin. His attending physicians wanted him to undergo bronchoscopy; the pulmonary people at the hospital referred them to a paper from Alabama that said, "Bronchoscopy is not helpful." The physicians said, "Look. This patient does not have *Legionella*. This man's X-rays look like PCP." The resident could not get the patient to agree to an HIV test. To make a long story short: after hearing the explanation of how important the HIV test was, the patient agreed to have it done. While waiting for the test results to come back, on a hunch, the patient was started on treatment with Septra and steroids. The next day his bronchoscopy, which was finally done, came back as positive for *Pneumocystis* pneumonia. Mr. Ortega was a 64-year-old divorced Hispanic man with five children who worked as a bartender.

His family was not surprised by the test result, which was one of the interesting lessons of this epidemic. The patient did not want to have the HIV test because, as it turned out, his main concerns were: (1) could he give AIDS to his son if he had it; and (2) what would happen when his family found out? Although this patient's family was not surprised, people often have peculiar ideas about HIV and about what the meaning of the virus is in their lives.

Minority Responses to AIDS

There are five issues that I think are important with regard to minority communities and HIV. The first one is blame. Anyone who has read about complicated genetic traces of the HIV virus which locate its origin somewhere in Central Africa understands that the African "origin of the virus" is fraught with symbolism for many Africans and African-Americans, who fear that blacks will be blamed for yet another scourge. The origin of HIV is one issue.

The linking of HIV with particular groups is another aspect of blame. Remember the consternation that greeted the change in designation of Haitians as a "risk group" in New York. That was probably the first instance of civil disobedience based on the CDC's designation of epidemiological category. But the fact of the matter is, that as a symbolic issue, the association of the HIV virus with Africa, with Haiti, or with "minorities" has great meaning for people. It is part of why people denied the epidemic—because in the midst of a decade in which minority communities were faced with multiple needs, the traditional leaders of those communities were loath to place high on the agenda an issue with which they personally had difficulty identifying. They were not particularly keen to hold up as the

poster child of the needs of black and Hispanic communities a gay man with AIDS.

The second issue, which is connected to the first, is drug use. Drug abuse stirs up many emotions in minority communities because, I think, they see drug abusers as both victims and victimizers. It is difficult, therefore, to get a non-ambivalent reaction to the subject of drug abuse and drug abusers, particularly during a decade which saw the rise of a very potent new drug—crack—and the resurgence of some old ones, with terrible consequences for both the health and the very life of people in many minority communities.

If a teacher, a lawyer, or a doctor of color is asked to lead a charge on behalf of a group for whom the community has, at best, mixed feelings, ambivalence often results. That is part of the reason why the leadership of minority communities has not been as active as the leadership of gay communities in the fight against the AIDS epidemic. The people in minority communities who have the virus are not as randomly distributed in the community as the people with the virus are in the gay community.

Moreover, the problem of drug abuse is related to issues such as needle exchange. In my view, the AIDS advocacy community has never understood how or why it is minority communities have had reservations and mixed feelings about needle exchange. The problem of drug abuse also has to do with the emotional and personal separation between the traditional "official leadership" of minority communities and the people who are most at risk for the virus.

I will return to this point in discussing the challenges in prevention of AIDS, because I believe that the official leadership of these minority communities has precious few connections to the people who are most at risk. It may be comforting to those of us who give out money for prevention programs to think that we are doing something by giving money to a black minister; but it remains to be seen just how much connection that black minister has with the segments of his or her community that are most at risk.

The third issue is homosexuality. It should come as no surprise that there is homophobia—bigotry—against homosexuals in minority communities, any more than it should that there is racism in the gay community. It would be nice to think that people who have suffered because of prejudice would somehow be immune to it themselves, but it is clear that our social cross-reactive immunity to prejudice is only partial, at best.

The AIDS epidemic has had two effects. One is to make apparent that there are large numbers of gay and bisexual men in minority communities, the existence of whom was largely denied by the official leaders of those communities. In some ways this has brought gays and minorities closer together. It is, for instance, hard for me to imagine the head of the NAACP appearing at a gay rights march fifteen years ago.

It is also true, however, that the association of AIDS in the public mind with homosexuality, and the fact that, even within minority communities, it is strongly linked to gay or bisexual sexual preference has continued to be one of the brakes on the coalescence of minority communities around AIDS as an important issue and the coalescence of the leadership of those communities, in particular.

If one examines the leadership of white Washington, or white Atlanta, the people who run major companies, who are publishers of influential newspapers, and so on, it is extensive and diversified. The leadership group is much less substantial in minority communities, and the fact that AIDS is linked to homosexuality, given that there is homophobia in these communities, has always been a concern.

The next issue that is important with regard to minority communities and HIV is suspicion. While I think that Dr. James Curran is an honest, competent, highly professional public servant, not all black people have the same confidence in the Centers for Disease Control.

It is interesting to note that Dr. Stephen Thomas—formerly of the University of Maryland, now at Emory University's School of Public Health—conducted a series of surveys of black households and churchgoers in the late 1980s and early 1990s to examine their views on what some might regard as wild, paranoid fantasies about AIDS. Dr. Thomas asked a total of 2,000 people in the Washington, D.C., area—including women in a community health center, households in Prince George's County, public housing residents in Prince George's County, college students in Washington, and male high school students in Washington—to respond to the statement, "I believe that there is some truth in reports that the AIDS virus was produced in a germ warfare laboratory." Sixty-eight percent of the respondents said that they either "agreed" or were "unsure" about this statement.

He asked for a response to, "I believe the Government is telling me the truth about AIDS." Among churchgoers in five cities—Atlanta, Charlotte, Detroit, Kansas City and Tuscaloosa, Alabama—44 percent disagreed with the statement that the Government was telling them the truth, and 35 percent were unsure.[7] On the basis of these results, it is likely that nearly four out of five African-Americans, when they received the Surgeon General's mailer on AIDS, looked at it with at least some doubt that they were being told the truth. There is a history—a legacy—of mistrust, not only of government institutions in minority communities, but also of medical research institutions as well, that has always been part of minority communities' response to the AIDS epidemic.

The last point I want to make about HIV snd minority communities has to do with the health care system in the United States and the inadequacy of care. In my view many of the debates that have come up within minority communities about testing, needle exchange, and various prevention and treatment strategies have been colored by the inaccessibility of adequate health care treatment resources for many people in those communities. Three years ago, in testimony to the National AIDS Commission, I said:

> Last week I saw a patient in our clinic [at Johns Hopkins], patient L.D. Mr. D. is a 34-year-old black man with an AIDS diagnosis who comes from the Eastern Shore of Maryland—approximately 2 1/2 hours away from Johns Hopkins. He was brought in by his AIDS case manager, an employee of the Maryland Department of Social Services, for assessment and management of a problem which could, and should, be managed in his local community. But Hopkins has become the de facto primary care provider for a patient who lives over 100 miles away because of two gaps: a lack of adequate medical services, and lack of social support. This is not primarily the fault of any individual—the man's case worker works hard and does the best she can. It is not the fault of individuals in the Maryland AIDS Administration and in other parts of state government—they are struggling valiantly and creatively to solve these problems. It is the fault of the *system* which was not prepared to cope with patients like Mr. D. even *before* there was an AIDS epidemic. He has an unstable personality, a history of drug use, and lives with his family, now no longer able to manage him, in a house with no running water. Herein lies one of the chief lessons of the AIDS epidemic: many of the patients we are now discovering to be HIV positive—many of the patients who will be diagnosed with AIDS in the coming years—are patients whom the private medical community was not eager to take care of even before this fatal, stigmatizing, transmissible disease made itself apparent.

Prevention

The most daunting challenge of HIV in the current era is that of prevention. Again, the accomplishment of this task in communities of color poses special issues. It should be remembered, first, that prevention of anything is a difficult job in American society. Political rhetoric not withstanding, the cultural and financial incentives to emphasize treatment over prevention are considerable. Where prevention has become incorporated into the health care system, it is usually in the clinical domain: immunizations, mammograms, pap smears, colonoscopies. Wherever there is a machine to be made, a reagent to be stocked, a procedure to be billed for, there are to be found both cultural and economic pressures pushing for the adoption of such practices. But the prevention of HIV has very few clinical links or financial incentives. It has, therefore, become like many other behavioral problems which now form the core of the public health tasks in the United States: smoking, violence, and so on. All of them are behaviors that are intensely personal, their causes are multifactorial, and scientific knowledge about them is still relatively immature.

In communities of color the challenge is even greater: the populations at greatest risk for HIV infection—intravenous drug users, their sexual partners, poor youth—are among the most alienated and disaffected elements of our society. There are, simply, very few institutional and organizational links by which the public health community can reach these populations. Indeed, one of the preconditions for the complex set of health and economic problems that young people, in particular, have is precisely the disintegration and disorganization of their communities. Many institutions which theoretically might serve as resources for information on HIV prevention—schools, work, family, church—may not have much meaning in the lives of those at greatest risk. The public health community then is confronted with a three-fold challenge:

(1) The development of a scientific basis in health communication, behavioral modification, and other disciplines to carry out HIV prevention effectively.
(2) The development of a far deeper understanding of communities at risk and of their existing institutions, together with the need to build new institutions (such as community-based organizations) to carry out the aforementioned prevention programs.
(3) The overcoming of decades-long suspicion of the government in general, and public health in particular, in precisely the communities whose trust is now needed the most.

Notes

1. Centers for Disease Control and Prevention, "U.S. AIDS cases reported through June 1993," *HIV/AIDS Surveillance Report* 6(1)(1994).
2. "AIDS among racial/ethnic minorities," *Morbidity and Mortality Weekly Report* 43(35)(9 Sept. 1994): 653-655.
3. Centers for Disease Control and Prevention, "U.S. AIDS cases reported through June 1993," *HIV/AIDS Surveillance Report* 6(1)(1994).
4. Ibid.
5. T. Dias, J. W. Buehler, K. G. Castro, and J. W. Ward, "AIDS trends among Hispanics in the United States," *American Journal of Public Health* 83(4)(1993): 504-509.
6. B. S. Menendez, S. Blum, T. P. Singh, and E. Drucker, "Trends in AIDS mortality among residents of Puerto Rico and among Puerto Rican immigrants and other Hispanic residents of New York City, 1981-1989," *New York State Journal of Medicine* 93(1)(January 1993): 12-15.
7. S. B. Thomas and S. C. Quinn, "Understanding the attitudes of black Americans," in J. Stryker and M. D. Smith, eds., *Dimensions of HIV Prevention: Needle Exchange* (Menlo Park, California: Henry J. Kaiser Family Foundation, 1993), 99-128.

Publishing AIDS Papers in the Early 1980s

Ruth M. Kulstad

From 1976 to the end of 1988 I worked as an editor at *Science*. Because of my interest and training in parasitology and microbiology, I handled many of the papers submitted on infectious diseases. When the first papers on AIDS started arriving in early 1983, they were put on my desk—along with papers on malaria, the myc oncogene, angiogenesis, agricultural economics, and many other subjects—and became largely my responsibility until they were published or rejected.

The first five AIDS papers that were published in *Science* came from the laboratories of Max [Myron] Essex, at the Harvard School of Public Health,[1] Robert Gallo, at the National Cancer Institute,[2] and Luc Montagnier, at the Pasteur Institute, Paris.[3] The paper from Montagnier described the isolation of a virus "clearly distinct from each previous isolate [of human T-cell leukemia virus, or HTLV]." This virus was initially referred to as lymphadenopathy associated virus, or LAV1,[4] and was later shown to be the cause of AIDS. These papers, published as a group on 20 May 1983, provided evidence of retroviral activity in the tissues of patients with AIDS or at risk for AIDS. Another group of papers, published a year later,[5] described the isolation and culture of a retrovirus called HTLV-III, provided evidence of its causal role in AIDS, and laid the groundwork for the development of tests for detecting antibodies to the virus. These four papers came from Gallo's laboratory, and have been the subject of much discussion.

Here I am going to describe what it was like publishing these and other AIDS papers at *Science* in the early 1980s. From what I read then and subsequently, and from what I heard from authors, reviewers, and other editors, conditions were somewhat similar at *Nature*, but may have been more structured at the medical journals, at least in the United States. What were the conditions at *Science* in the early 1980s?

First, there was a perennial shortage of space in the journal for reports of original research. Lack of funds prevented the printing of more pages per week. Many good papers were therefore rejected; of those we accepted, most had to be shortened before publication by the authors and editors, sometimes with the help of reviewers.

Second, since *Science* is an interdisciplinary journal, we had to strive for balance of subject matter. Papers in the biological sciences competed not only with each other, but with papers in the physical sciences. If we wanted to accept a paper, which usually meant sending it back to the authors for revision, we would put the manuscript in a pile in John Ringle's office and make a note of it on a list on his desk. Ringle was the Assistant Managing Editor, and he kept track, on paper, of the number of manuscripts per week being accepted and their subject areas. If it looked as though we were accepting too many papers, or too many on one subject, Ringle would pull a few manuscripts from the pile and discuss them with the editors handling them. Sometimes the discussion extended to Philip Abelson, the Editor of

Science, but usually we could decide with Ringle which ones to keep. This system had a flaw, however. Editors sometimes "forgot" to put their papers in Ringle's office before sending the "accept-pending revision" letters to the authors. Thus, we periodically accumulated large backlogs of accepted but unpublished manuscripts. On several occasions we published announcements in the journal about our predicament and, for a week or two, rejected all manuscripts. A new system evolved in 1984: we held a weekly space meeting. A few of the editors gathered in Abelson's office and discussed the merits and weaknesses of the papers we wanted to accept. Depending on the backlog, we would select perhaps three or four for publication, increasing the number as the situation improved.

Third, the system for identifying reviewers was crude. The central reviewer database consisted of a mechanical punched-card file that was time-consuming to update and cumbersome to use.[6] Most of the editors maintained their own reviewer files—on cards, in notebooks, or in looseleaf binders. My own files, dating from 1978, consisted of copies of letters of submission filed by the subject of the paper.[7] Most such letters stated the title of the paper, the names of all the authors, and the main purpose of the study, and listed four or five potential reviewers, as requested in *Science*'s Information for Contributors. These letters were copied (time permitting) when the manuscripts came back from review, and were annotated with the names of the reviewers actually used, comments on their performance, and the probable fate of the paper. These records were supplemented with names and information gleaned from discussions with authors and reviewers, from talks with other editors, and from papers published in other journals.

Fourth, it was *Science* policy that all manuscripts (in practice, probably 95 percent) submitted should receive outside peer-review; only the most obviously inappropriate papers, with the agreement of Ringle, were rejected without outside opinions. Starting in about April 1983, a few were rejected after discussion of the substance of the work with a potential reviewer. The submission rate for research reports in 1983 was 75 to 115 per week.[8] Averages taken for a four-week period in October-November 1982 showed that in any given week 815 manuscripts were on-hand, including 80 that were being sent out to reviewers for the first, second, or sometimes the third time.[9] There were fewer editors then than now. In 1983, five of us, including Ringle, selected reviewers and evaluated the reviews; copy editing and checking authors' galley corrections were shared among us and four to six others. Ringle distributed manuscripts to us according to our interests and expertise, but there were always more subjects than there were editors; specialization in just a few subjects was not possible. However, the system was evolving. Additional editors started selecting reviewers in late 1983, and many other organizational and procedural changes were made in 1985.

It was against that background that *Science* started receiving manuscripts on AIDS in 1983. All the editors had, of course, been reading about AIDS in other journals, as well as in the popular press and in newsletters from blood banks and other organizations. We were therefore aware of current thinking about the disease.

My comments below are based largely on memory, supported by browsing through the literature of the early 1980s and by reference to personal notes, mostly undated, found among reprints and Xerox copies of published papers that I kept while at *Science*.

The Earliest AIDS Papers

AIDS papers were submitted sporadically at first, increasing to several papers per month by mid-1983 and sometimes several per week by late 1984. There was no shortage of ideas on the cause, or causes, of the disease, and the ideas submitted to *Science*, sometimes in the

form of manuscripts, sometimes as telephone calls from prospective authors, reflected the views of society at that time (e.g., that AIDS was due to promiscuous homosexual activity or the use of recreational drugs) as well as recent developments in various fields of biology. Some of the earliest papers suggesting an etiology came more in the form of proposals than research reports. They were too long, and often inappropriate, to be published as Letters to the Editor, and contained too few experimental data to be considered as reports. These papers were usually discussed with appropriate peer-reviewers on the outside and then rejected; some appeared subsequently in other journals or in the *AIDS Memorandum.*[10]

Papers came from two camps initially: a small one proposing a multifactorial etiology for AIDS, with no single transmissible agent being responsible, and a large one supporting the view that a specific infectious agent was the cause. The small camp, focusing on the gay population, suggested that the immunosuppressive effects of seminal fluid and, possibly, amyl nitrite (poppers) or other recreational drugs, together with repeated infections with cytomegalovirus (CMV) leading to reactivation of Epstein-Barr virus (EBV), reduced the ability of the immune system to ward off opportunistic infections or cancers and thus led to AIDS.

The ideas of the small camp were not without foundation: research on infertility had shown that seminal fluid could be immunosuppressive;[11] the use of poppers did seem to be a link that differentiated gay men who developed Kaposi's sarcoma (KS) from those who did not;[12] and there was plenty of evidence that CMV and EBV, by infecting T cells and B cells, respectively, could lead to changes in the immune system.[13] Thus, until the presence of a transmissible agent could be proved, many reviewers were open to these ideas; and, evidently, editors were willing to publish them.[14] *Science* received very few papers from the small camp; one of them, focusing on the immunosuppressive effects of seminal fluid, was published in April 1984.[15]

Members of the large camp proposed that AIDS was caused by a specific transmissible organism, possibly a mutated form of a known virus or rickettsia, or a previously unknown virus, bacterium, or mycoplasma. Both before and after publication of the FeLV/HTLV/LAV papers on 20 May 1983,[16] *Science* received several papers from this camp that were of interest, two of which I mention here.

Among the "emerging diseases" of that period was an acute enteritis in domestic dogs caused by canine parvovirus (CPV) type-2. This virus was first observed in the United States, Europe, and Australia in the period 1978-82. It was unknown before that time, and was believed to be a mutant form of a pre-existing virus of carnivores.[17] Its sudden appearance in dogs suggested that another mutant form might be found in humans, and led the authors of the paper *Science* received to search for CPV-related antibodies in AIDS patients. However, the results were negative, and *Science,* like most journals, seldom publishes negative results. The study was useful, nonetheless, if only to show others that that path had been taken, and we were pleased to see it appear in the *AIDS Memorandum.*

Another emerging disease at that time was known in the Washington, D.C., area as Potomac horse fever. A member of the family Rickettsiaceae was suspected as the cause, but it was proving difficult to isolate.[18] While the search was on for that agent, several investigators pursued the possibility that another rickettsia might be causally related to AIDS, and submitted a paper to that effect. The paper lacked convincing data, however, and was rejected.[19]

A problem with several papers submitted around this time was that the pathology that might be expected from infection with the organisms proposed as causing AIDS bore little resemblance to the pathology observed in AIDS patients. However, the fact that some viruses, such as EBV, can have a variety of effects depending on host and geographical conditions made several reviewers feel that the papers should be given consideration.

From the telephone calls we received from prospective authors it was evident that numerous individuals were searching for the cause of AIDS—in the literature if not in the laboratory. Some were convinced they had the answer and were very emotional about their ideas, but few had data. Such calls continued long after *Science* published the four papers reporting the isolation of HTLV-III from the Gallo laboratory in 1984, since many authors believed that this new virus was not the whole answer to AIDS.

Reviewers for the Early AIDS Papers

Unless it was clear that a paper was going to be controversial or that it covered more than two areas of specialization, most papers submitted to *Science* went to two peer-reviewers, at least initially. In view of the unknown etiology of AIDS, and in view of the content of the earliest AIDS papers, it was sometimes unclear who the authors' peers might be. In most instances, however, the appropriate reviewers seemed to consist of one person who was working on, or was knowledgeable about, the particular agent or condition being discussed and one person, often an immunologist, who had some clinical experience with AIDS patients.

For papers from the small, or minority, camp, one might expect that finding reviewers would be a challenge, but this proved not to be the case. Most reviewers were willing to consider any possibility, or at least they were curious to see what others were thinking. What was surprising was that at least two potential reviewers, appropriately qualified, were unwilling, even in 1984, to entertain the possibility that an infectious agent was responsible for AIDS, and they declined to review papers proposing such an etiology.

Reviewers, when called on the telephone, were particularly helpful in providing additional names of well-qualified people in their own and related fields. In mid-1984 two authors/reviewers, one on the East Coast and one on the West, recognizing the difficulty of finding appropriate reviewers to evaluate papers on a new disease, each sent *Science* a list of about 60 researchers in the fields of general virology, adenoviruses, oncogenes, growth factors, leukemia, gene expression, and cytogenetics. Many of these people were called upon to review manuscripts in the years that followed.[20]

There was a general *Science* policy that no more than one reviewer suggested by the authors should be used; however, use of any of the authors' suggestions varied greatly from field to field, as well as from author to author. A few authors tended to suggest close colleagues as reviewers; some suggested only Nobel prizewinners; and some, as though to test us, suggested people far from the paper's main topic. However, many authors listed the very reviewers the editors would have selected without seeing the submission letter, and these reviewers might or might not be used; there were often many alternative reviewers in the same area that could be selected.

It would have been easy, of course, to rely on a small number of tried and trusted reviewers in each field rather than to seek opinions from an ever-increasing range of individuals.[21] But we were aware of the fact that use of the same reviewers repeatedly can result in the stifling of originality, and that editors have a role in allowing new ideas to surface in the literature. We were also aware of other ways in which we could influence the outcome of the review process. For example, we knew of reviewers who nearly always recommended rejection, just as we knew of others who liked everything. Such individuals may have represented the extremes of closed- and open-mindedness, but there was one, at least in our folklore, who rejected everything because he had once had a paper of his own rejected by *Science*. There was no systematic recording of reviewers' performance other than in our own records,

and cautionary information on reviewers did not always get to other editors who might be using the same individuals for the first time. This lack of information transfer may not have been important, however, since it was also the case that the quality of a reviewer's comments could vary tremendously from one manuscript to the next, not just because of differences between manuscripts, but because of timing and commitments of the reviewer.[22]

Reviewers were always called before being sent manuscripts to review. The usual procedure was for the editor to write the names of four or five selected reviewers on a sheet of paper, indicate an order of preference or the aspect of the paper they were to be asked to review, and send the sheet along with the manuscript to the telephone room. Three to five telephoners spent each day calling potential reviewers. If the reviewers we had suggested recommended other individuals for a manuscript, the telephoner, depending on the editor's instructions, could either follow those recommendations or return the paper to the editor for further suggestions. The telephone room was a time-saver for the editors, but, because of the number of reviewers being called each week, it was not so for the reviewing of manuscripts. Five to ten or more working days might elapse before two reviewers, or, for some manuscripts, three or four reviewers, could be found. Some of the editors therefore made their own calls to reviewers, particularly when they wanted to get a potentially "hot" paper out fast, or needed information regarding reviewer bias or conflicts of interest, for example. For the early AIDS papers, I made most of the calls to potential reviewers, and I received much valuable guidance.

Decision-Making

Reviewers received instructions that read: "We want to publish highly significant, technically sound papers. A paper should have news value for the scientific community, unusual interest to the specialist, or broad interest as an interdisciplinary problem." These were also the criteria on which the editors based their decisions, although there was some variation in their application, depending on the discipline. We had no formal discussions of these criteria, but it was clear from conversations we had over particular papers that we all had common principles and common goals. We all wished to advance science and maintain high standards, and, although we might not have seen eye-to-eye on every paper, we respected each other's opinions.

Time, or lack of it, prevented all the potentially acceptable papers from being passed around to all the interested editors. More likely to be passed around to one or two other editors were papers being considered for rejection. Discussions or exclamations about papers were usually with Ringle or with the occupant of a nearby office who did not appear to be drowning in manuscripts at the moment their attention was needed. Abelson was also available as a sounding board, willing to listen and to provide balance and objectivity when circumstances indicated. He had had more experience than most of us in predicting the long-term consequences of decision-making, and it seemed to us that in his view the occasional misjudgment was of little long-term consequence. While he might chide us on occasion for faulty thinking or for an inappropriate statement made to an author or reviewer, he would give us the benefit of the doubt and support us in our dealings with detractors. This was important in maintaining a certain cohesion among the editors and provided a secure background from which to operate.

The editor's role was to find appropriate reviewers and oversee the reviewing process, and then make decisions based on the reviewers' comments. From the papers with the best recommendations, and, occasionally, from those for which, with good cause, we had over-

ridden a less-than-enthusiastic review, we made our selections. We picked some papers for their breakthrough information;[23] some for the high quality of the work and the sound results;[24] and some for their novel ideas.[25] Some papers were picked because they represented a giant step forward in a field that moved rapidly; others were picked for their small step forward in a field that seldom moved. We tried to envision the long-term as well as the immediate impact of papers on their own fields and their relevance to other fields. And we believed that the subject mix of the papers selected should be fairly representative of the subjects on which papers were being received. In decision-making for the early AIDS papers, the potential immediate impact of the work was one of the primary considerations; one had to hope that the organism or condition being proposed as the cause of the disease would indeed prove to be the cause. Then, in retrospect, the work would be a breakthrough—and a giant step forward. But first one had to be willing to risk publication of the novel idea.

A policy that developed between 1983 and 1984 was that all papers ready for consideration in a given week, that is, all papers that the editors wanted to accept and for which we had at least two reviews on which decisions could be based, should indeed be considered for acceptance that week. They could not be held over until the next week, or the next, on the chance that there might be fewer papers later on with which they would have to compete. We usually followed this policy, and it contributed to some of the unevenness in the quality of papers accepted—and to the rejection of some good ones.

At least to some extent, therefore, whether a good paper was accepted or not depended on the luck of the draw. Truly excellent papers were usually recognized and given priority; they were accepted without question. But there are well-known examples of papers in several fields that were turned down and later recognized as important; the reviewers may not have expressed particular enthusiasm about the work, or the editor(s) may have missed the main point of the paper or not understand its broad implications.[26]

In the belief that neither we nor our reviewers were infallible, *Science* had a policy allowing multiple resubmissions of rejected papers. Most such resubmissions were reevaluated by the editors and rerejected; some were sent back to the original reviewers; others were sent to additional reviewers. The use of multiple reviewers for a single paper had drawbacks, however, since each one was likely to find something different to criticize and it was possible to end up with multiple rounds of revision. The paper might have been perfect in the end, but there was something to be said for allowing the readers, the "post-peers," to judge the papers themselves. Should the privileged "pre-peers" be the only ones able to see the quality of work being done by an author, a group, or a laboratory before it is perfected as a result of outside advice?[27]

The First HTLV/LAV Papers

Arrival.

Many authors seeking rapid publication of a "hot" paper would call *Science* before submitting the manuscript and ask to speak to the Editor (Abelson) or the editor likely to handle it. Such calls were encouraged: an author who found the editor less than enthusiastic about the paper could consider sending it elsewhere; an editor interested in seeing the paper could prepare for its arrival—by reducing the height of the pile of manuscripts on the desk, for a start, and thinking about potential reviewers. It was through a call from Robert Gallo that *Science* first learned that he and his colleagues at the National Cancer Institute and Max Essex with colleagues at the Harvard School of Public Health and the Centers for Disease

Control in Atlanta had obtained evidence of HTLV in serum samples and cells from AIDS patients. This call led to the submission of the two papers from Gallo mentioned earlier that were published on 20 May 1983, with two from Essex and, at the last minute, one from Montagnier.[28]

Gallo's call came a few weeks before he submitted the first (Gelmann et al.)[29] of his two papers. He explained that the second (Gallo et al.)[30] might not be ready for a month, and acknowledged that both papers had weaknesses. He said he had seen Max Essex at a recent meeting and that Essex had told him about a paper (Trainin et al.)[31] on feline leukemia virus (FeLV) that he had just submitted to *Science*. Essex also told Gallo about another paper (Essex et al.)[32] that he expected to have ready for submission in a few weeks. Gallo said that he and Essex had agreed that, in view of the seriousness of the AIDS epidemic and the likelihood of its being caused by an HTLV, publication of four papers together, all pointing to a retroviral etiology, might have a greater impact on the scientific community than publishing each paper alone. We discussed this possibility. It meant that the Trainin et al. paper might have to be held for several weeks before the other papers would be ready, and that there would be a scheduling problem: there was no knowing whether all four papers would be accepted or, if they were, when they would be ready. Since two of the papers were still being written, the situation was somewhat hypothetical. After calling Essex, both to verify his agreement with Gallo and to warn him of the potential delay in publication of the paper by Trainin et al., I mentioned to the Production Editor, Ellen Murphy, that we might want to publish four papers together, if, eventually, they all came in.[33]

The fifth paper of the group, from Montagnier's laboratory (Barré-Sinoussi et al.), was sent to Gallo before it came to *Science*.[34] Gallo called in mid-April to say that his second paper (Gallo et al.) would soon be ready and that he had been talking to Montagnier, who had said that he had isolated a virus from a patient with lymphadenopathy and that he was writing a paper to send to *Nature*. Gallo told Montagnier that he, too, had isolated a virus, and was sending two papers to *Science*; he suggested to Montagnier that he might want to have his paper published with these two and with the papers from Essex et al. Montagnier agreed and said he might submit his paper to *Science*. Gallo called me again some days later to say that his second paper was ready for submission, and that he had just received the paper from Montagnier. He wondered whether I had also received a copy of the paper. I had not. Gallo said he was not sure why Montagnier had sent it to him instead of directly to *Science*, other than perhaps Montagnier did not know whom, at *Science*, to send it to, or he wanted Gallo to see it first. Gallo also said that the paper was lacking an abstract, and that since Montagnier was going to be traveling, he had agreed to prepare one for him after reading the paper. In the meantime, he would send Montagnier's paper along with his own, so the two papers could be logged in and reviewers found.

Processing.

Among the factors considered in deciding how to proceed with this group of FeLV/HTLV/LAV papers were the progress of the epidemic and the public health implications. There was already good evidence to suggest that AIDS was caused by a filterable virus, and, of the papers *Science* had received or heard about, these appeared to be the closest yet to providing evidence of a cause. Much was already known about FeLV; the paper by Trainin et al. was a step forward in showing the effect of FeLV on the cat's humoral response. This paper, which had been revised and accepted before the last two papers (Gallo et al. and Barré-Sinoussi et al.) were received, could stand on its own. It made no mention of AIDS, but the implications were clear. Individually, the HTLV and LAV papers were weak;

the reviewers knew it, the authors knew it, and so did the editors. But side-by-side, with the FeLV paper as background, they supported the view that studies of a possible retroviral etiology were worth pursuing. Publishing the papers in *Science* might enable the community of basic researchers, many of whom do not read medical journals, to make use of this lead. If the papers were going to be published, they should be published promptly.

Reviewers of potentially hot papers at *Science* were sometimes asked to provide initial comments, over the telephone, within a few days of receiving the manuscript, and to follow these with a written review. From such initial comments the editor could usually get an idea of whether or not a paper was likely to be publishable, and whether or not to start looking for a publication date. The reviewers of the last two papers in this FeLV/HTLV/LAV group responded rapidly; they recommended some revisions, and most of these were made. At some point, Gallo provided an abstract for the Barré-Sinoussi paper. The first three papers of the group had progressed at a more normal pace. When the last two were sent to the printer they were typeset (almost?) overnight; one to three weeks was the usual turnaround time for reports being typeset. The main problem was finding the location of Montagnier, so we could send him proofs. Repeated calls did not find him in Paris. Nevertheless, one set of proofs was sent to him there, in the hope he would soon return; another set was sent to Gallo's laboratory, because there was a chance that Montagnier might turn up there. After several days of anxiety at *Science* and some frantic calls to France, he was located and he did approve the proofs.

Publication.

The rapid publication of "hot" papers was not unusual, but such papers were usually not in groups, unless they formed parts of special issues, such as those on the Pioneer encounter with Saturn or the Voyager mission to Venus. With the help and cooperation of the production department, single hot papers could be published more rapidly than groups of such papers. Each issue of the journal was planned two to three weeks in advance, as far as the number of pages for each section and the actual content of the articles and reports sections were concerned. The five FeLV/HTLV/LAV reports would be expected to take up a certain number of pages, and that number of pages would be reserved in the first available issue, or in an issue for which the papers were likely to be ready. If one, or more, of the papers was subsequently found to be unacceptable or to need drastic revision before acceptance, or if the proofs were not approved by the authors, other papers of equivalent length would have to be ready to fill the space.

If all went well the papers might be ready in three to four weeks from the date the last two were received (19 April 1983). The issue of May 13 might be risky. Murphy mentioned May 20 as a possibility, but that would be the Book Issue, which might not have much space for reports. We would not know the exact length of the last two reports until all revisions had been made and the proofs were received, but we could make a good estimate. Would the people we expected to read the papers see them at the end of the Book Issue? We hoped so, because that was the issue in which we planned to publish them, and did so.

From Mid-1983 to Mid-1984

The United States Blood Supply.

Although interest in retroviruses increased after publication of the first HTLV/LAV papers, many people were skeptical about the possible retroviral etiology of AIDS. There was much

discussion of cofactors, and of the possibility that HTLV too was a cofactor. The incidence of Kaposi's sarcoma in gay patients with AIDS was especially confounding, and lent support to the idea that an additional transmissible agent was circulating in the gay community. AIDS papers submitted to *Science* in the last half of 1983 and on into 1984 reflected these uncertainties. Some papers proposed alternative etiologies, some discussed opportunistic infections, and some focused on the epidemiology of AIDS; most, however, were devoted to retroviruses, particularly HTLV and the simian viruses.

Concerns about the United States blood supply in the early 1980s stemmed, in part, from the recent (July 1982) licensing by the Food and Drug Administration of a vaccine against hepatitis B virus (HBV). The vaccine was based on viral envelopes (HBsAg) extracted from the plasma of HBV-infected blood donors. Similarities in the modes of transmission of AIDS and hepatitis had been noted early in the AIDS epidemic, and it seemed likely that the AIDS agent, whether or not it was HTLV, would also be found in donated blood. Others such as the American Association of Blood Banks disagreed. *Science* received on August 15, and published on 9 September 1983, a paper reporting the presence of HTLV membrane antigens in serum samples from hemophiliacs with no known risk of AIDS except for having received blood or blood products.[35] Among the authors of this paper were four from the Centers for Disease Control, including Donald Francis, and four from the Harvard School of Public Health, including Max Essex. Francis and Essex, on the basis of their work with FeLV, had been active in trying to convince HBV researchers of the causal relation between HBV and primary hepatic carcinoma.[36]

Another paper on HTLV membrane antigens, this time in serum from patients with transfusion-associated AIDS and their donors, was received on February 27 and published on 23 March 1984.[37] Like the earlier paper, many of the authors were from the CDC and from the Harvard School of Public Health, and, although the data were presented with alternative interpretations, it appeared that a concerted effort was being made to alert the public, if not other parts of the government, to the risks of donated blood.[38] Was *Science* being used for political purposes? Undoubtedly. *Science*, like other journals, is a forum, and it is the nature of a forum to present ideas. If authors have sound scientific evidence of a risk associated with the blood supply, for example, or of a benefit likely to stem from an advance made by researchers in industry, then it is appropriate for *Science* to present the authors' data; the readers can judge for themselves.[39]

Simian AIDS.

The simian AIDS papers that *Science* received were among the most challenging to deal with.[40] The people best qualified to review them always seemed to have strong opinions on the nature of the viruses being isolated, and these opinions always seemed to conflict with those of the paper for which reviewers were needed. It was possible, eventually, to find reviewers who felt they could be objective, and their comments were always helpful—but they were also extensive. They often included, sometimes as part of the review and sometimes in a separate letter to the editor, the history of every subhuman primate retrovirus at every United States regional primate research center as well as the history of every disease these viruses caused. These histories varied from reviewer to reviewer, as well as from author to author, in the early 1980s. Subsequently, the source of some of the problems with these papers was removed by the finding that two retroviruses, rather than the one previously supposed, were circulating at the New England Regional Primate Research Center.[41]

The papers on simian retroviruses, like those on HTLV antigens in the blood supply, bring up the issue of finding reviewers for papers in relatively small fields. Who is appro-

priate to review a paper in a small field where everyone not only knows everyone else but is also probably collaborating with some of them or has done so in the past? To be reviewed properly, a paper in a particular field needs to be seen by someone who understands the current problems in that field, but the only people who do understand those problems are the people in that field. One potential reviewer for a simian AIDS paper, who was not currently associated with one of the primate research centers and thus felt unqualified to review the paper, commented that "You need a real 'monkey person' to look at those types of papers." Indeed, the monkey papers needed monkey people to review them. Likewise, the papers demonstrating the potential risk of the blood supply needed people, or at least one person, associated with a blood bank to review them. Many such people were still declaring the blood supply to be safe, however. By calling around it was possible to find the names of a few people in blood-banking who acknowledged that there was a problem with the nation's blood supply. By selecting these people as reviewers, was the editor influencing the outcome of the review process? Of course. Would it have made sense to send the papers to those who were denying the existence of a problem?

AIDS in Africa

The pandemic nature of AIDS was beginning to be appreciated in 1983, but it was not until 1984 that *Science* started receiving papers on the incidence of AIDS in different parts of the world and on geographic variations in its clinical expression. Two of the earliest papers we received on AIDS in Africa were rejected, one of them with great reluctance. The reviewers requested more data, but the collection of such data, as pointed out by the authors, would take a year or more. The data were indeed preliminary, but they were also highly indicative of a much greater problem internationally than was currently recognized. This was an instance in which one was forced to consider the possibility that the reviewers did not believe, or did not want to believe, the data. Had the editor selected the wrong reviewers? Should the paper have been sent to further reviewers? (I believe it was sent to a third reviewer.) Other *Science* editors who saw the paper thought there were other important papers in-house competing for space. The paper was subsequently published in another journal. Would it have had a greater impact if it had been published in *Science*? Probably not; it had quite an impact without the help of *Science*.

The HTLV-III Papers

The HTLV-III papers that were submitted to *Science* on March 30 and published on 4 May 1984[42] came with several weeks' warning. Gallo called to say that the virus was growing and that he expected to have four papers ready soon. Four papers from the same laboratory would present a problem. Why could they not be condensed into one or two? Gallo said that the work constituted four separate studies, with four different authors needing the credit of first authorship. Like some other authors, he reminded us of the existence of other journals that would like the papers. After discussing the situation with Abelson, we decided to push for getting the papers reduced to two, but not to push so hard as to lose them. It was always possible that the reviewers would recommend rejection or would insist on the papers being combined, but at least we wanted to see them first.

There were times when we took risks, and this was one of them. When the papers arrived on March 30 there were still four of them. They were immediately sent out for review, and the reviewers responded rapidly. One reviewer, who was looking at two of the

papers, called up within a day or two of receiving them to say we should "go ahead, something has to be done [with regard to the disease]." After a call was made to another reviewer, and after some discussion with Abelson and Murphy, we decided to schedule the papers for the first issue in May. This meant they might have to be edited and sent to the printer before we received all the written reviews, and that some revisions, even if they were extensive, would have to be made in proof. If any of the papers subsequently received negative reviews and had to be rejected, *Science* would have to absorb the costs of typesetting unpublished papers.

The reviewers gave us their evaluations on the telephone or in written comments, or both. Corrections were done in proof, as was some more editing, in consultation with the authors, and the papers were published as scheduled; but this was one day after they were announced to the public by Margaret Heckler, Secretary of the United States Department of Health and Human Services.

Embargoes

Like many other journals publishing peer-reviewed manuscripts, *Science* asked authors not to release their papers to the press or the public prior to their publication. There were two embargo release times: Thursdays after 4 p.m., for the broadcast media, and a.m. on Fridays for the written media. Authors who broke these embargoes more than a week before publication date ran the risk of having their paper pulled from the issue for which it was scheduled. If it was too late for the paper to be pulled, the author might be informed that papers from his or her laboratory would not be considered for publication in *Science* for a period of three or four years. In one instance, the authors of an AIDS paper held a press conference to announce their results before they had even submitted the paper for publication. One of the authors called up soon after the press conference to ask if *Science* would be interested in publishing the work. *Science* would not be interested, in spite of the paper sounding potentially publishable.

Press releases for important papers that were about to be published in *Science* were prepared by the Communications Department of the American Association for the Advancement of Science (AAAS), often in cooperation with the editor handling the paper. The task of writing the releases on AIDS papers usually fell to Jeff Teramani, who was adept at handling calls from the press and admonishing authors who broke embargoes. Together with proofs of the abstracts and, if not the complete papers, information on how such could be obtained, the press releases were mailed to about 40 journalists who regularly wrote about science for the major newspapers and radio and television stations and who had agreed to observe the *Science* embargoes. Journalists who broke the embargoes were taken off the mailing list.

Embargoes serve three main purposes: (1) they allow the peer-reviewing and manuscript selection processes to be accomplished without the interference of extraneous opinions; (2) they allow journalists receiving press releases time to read the paper and talk to the authors or others in the field and thus to write well-balanced stories; and (3), for medically related papers, they enable physicians, if they subscribe to the journal and receive it promptly after publication, to be as informed about the work as their patients, in the event that they are questioned about a new treatment, for example.

The ethics of embargoes and the occasional need to break them were discussed periodically at *Science*, as at other journals,[43] and it was generally agreed that for papers that could be critical to the practice of medicine or to the public health, the breaking of embargoes should be permitted by agreement among editors, authors, and institutions. AIDS papers

posed a problem because AIDS was indeed a matter of public health, but relatively few of the papers published in *Science* would have had any immediate impact on the public health. Rather, their direct impact would have been on the scientific community, stimulating further research. Exceptions, i.e., papers deserving early release, would have included those demonstrating the presence of HTLV membrane antigens in serum samples from blood donors. In these instances, one could say that the public needed to be made aware of a risk that part of the government, as well as the blood-banking industry, was still unwilling to acknowledge. But even papers granted early release must have completed the review process and have been accepted for publication.

From Mid-1984 to Early 1985

At about the same time that the four HTLV-III papers from Gallo's laboratory were being reviewed and prepared for publication, four papers on LAV were submitted[44]: on April 27 (Feorino et al.), May 1 (Klatzmann et al.), May 4 (Kalyanaraman et al.), and May 14 (Montagnier et al.). The two from Montagnier's lab (Klatzman et al. and Montagnier et al.) dealt with the biology of LAV and its adaptation to growth in EBV-transformed B cells. The other two were from the CDC, which was then collaborating with Montagnier and his colleagues and listed members of the Pasteur Institute as authors. One of these CDC papers (Feorino et al.) was again pointing to contamination of the United States blood supply. The other by Kalyanaraman et al. described the use of a radioimmuno-precipitation assay, based on the core protein (p25) of LAV, to determine the prevalence of antibodies to LAV in serum of patients with AIDS or pre-AIDS, homosexual men, laboratory workers, and blood donors. Also in May (May 31), *Science* received a paper from Jay Levy's laboratory[45] reporting isolation of an AIDS-associated retrovirus (ARV) from patients with AIDS in San Francisco.

These further demonstrations of the association of HTLV-III and LAV with AIDS, together with the isolation of ARV, supported the view that the new virus, or viruses, had more than an opportunistic role in AIDS, and opened up new avenues for research—particularly for those with adequate funds and with access to the new virus isolates. However, the lack of political interest in AIDS, at least in the United States, meant a lack of funds for AIDS research.[46] The number of AIDS papers submitted to *Science* did increase slightly during this period, but most of the papers came from scientists who were already doing AIDS research or who were studying other retroviruses, including HTLV-I and -II, bovine leukemia virus, and the lentiviruses. The recognition that the AIDS virus was more closely related to the lentiviruses than to HTLV-I and -II was reflected in papers submitted to *Science* in the last half of 1984.[47]

With evidence, if not proof, of the cause of AIDS, some researchers started more focused searches for potential cures, mostly in the form of viral inhibitors. A paper on suramin,[48] an inhibitor of reverse transcriptase, was the first on this subject submitted to *Science*, but it was followed by many more, few of which were published, at least in the early 1980s. Like authors of the earlier papers proposing etiological agents, some of the prospective authors of papers proposing cures became very emotional when they felt that their papers or ideas were unappreciated by *Science*.

Another area that began to develop was that of modeling the course of the AIDS epidemic on the basis of different estimates of the latency, or incubation period, of the virus. Between mid-1983 and mid-1984, estimates of the maximum latency period increased from about one year to up to four years. In a paper received by *Science* in May 1985, the authors

had calculated the latent period on the basis of data from blood transfusion recipients who were developing AIDS and in whom the date of probable infection was known. These authors placed the mean incubation period at about 4.5 years, with a 95 percent confidence interval of 2.5 to 14.2 years. In calculating these results, the authors had recognized that earlier models had not allowed for the fact that transfusion recipients and other individuals who were developing AIDS at that time were likely to be those with short incubation periods. An approach was needed that would take into account those individuals with long incubation periods who would not yet have been identified as having AIDS. This was an eye-opener, but the reviewers argued for several weeks (or was it months?) about the statistical method used to derive the data. Eventually, with the concordance of *Science*'s consulting statistician, the authors sent the paper elsewhere.[49]

Statistical reviewing had been one of *Science*'s weak points until 1982, when, at the instigation of Sylvia Eberhart, who was editing papers in the social sciences, and as a result of pressure from statisticians at several institutions, Abelson hired Science's first staff consultant in statistics, Joseph M. Cameron. Authors submitting papers to some of the medical journals, such as the *New England Journal of Medicine*, were used to having their manuscripts examined by statisticians; authors submitting papers to *Science* had yet to adjust to this intrusion.

Cameron focused initially on social science papers, and then started examining the research designs and statistical methods used in published and unpublished papers in the biological and physical sciences. His role evolved from one of an advisor to the editors when they consulted him to one of his overseeing the statistical quality of all papers targeted for revision with a view to acceptance.

The reaction of some authors, among them many cell and molecular biologists, was one of shock. Some were indignant when they were asked to indicate in their manuscripts the number of times they had repeated an experiment and the level of variablity of the results. Among the authors of AIDS papers, some of those doing CAT (chloramphenicol acetyltransferase) assays could hardly believe that the percentage variation between experiments was relevant to anyone but themselves. However, Cameron's advice was also appreciated, perhaps most of all by the author of an AIDS paper who, at Cameron's request, arrived one day with several pages of raw results. After studying them briefly, Cameron could see many good data in the author's records that supported the conclusions even more strongly than those presented in the manuscript. The author explained that the presentation reflected a conservative approach to interpretation of the data. Upon Cameron's recommendation, the analysis and presentation were changed and the impact of the paper was correspondingly increased. Over time, the requirement that authors give some indication of the uncertainty of their results gained acceptance, and we began to see the kinds of statements required by *Science* also appearing in other journals.[50]

Conclusion

The period 1984 to 1985 was one of transition at *Science*, with Philip Abelson retiring at the end of 1984 and Daniel Koshland assuming the editorship in January 1985. There was a trend during this period toward greater specialization among the editors, and a change in policy that enabled the editors, with the help of a newly appointed Board of Reviewing Editors, to reject about 40 percent of the papers submitted without subjecting them to in-depth review. More editors were hired, making it easier for all of them to attend scientific meetings, and the weekly "space meeting," at which the editors decide

which papers should be accepted, became an institution.

This more structured approach to publishing, compared with the lack of formality that characterized *Science* in the early 1980s, makes submission of manuscripts to the journal somewhat less of a gamble, but no change within budget limits can totally eliminate the risk of a good paper being rejected or a poor one published. Editors can make mistakes, and so can reviewers. What is important, for the progress of science, is that good work gets published somewhere, preferably with little delay, and that poor work, if it does get published, is shown to be poor, also with little delay.

Many journals besides *Science* had a role in disseminating the results of AIDS research in the early 1980s. Most of them published these results without undue delay. Good papers turned down by *Science* appeared promptly in other journals, and poor papers that were published were shown to be poor. The system was working well then, and, although there will always be room for improvements, I believe it still is working well now.

Acknowledgments

I thank Elia Ben-Ari, Ruth Guyer, Katherine Livingston, and Georg Springer for critical comments, and Nancy Hartnagle for permission to quote from her unpublished manuscript.

Notes

1. Z. Trainin, D. Wernicke, H. Ungar-Waron, and M. Essex, "Suppression of the humoral antibody response in natural retrovirus infections," *Science* 220(1983): 858-859; M. Essex, M. F. McLane, T. H. Lee, L. Falk, C. W. S. Howe, J. I. Mullins, C. Cabradilla, and D. P. Francis, "Antibodies to cell membrane antigens associated with human T-cell leukemia virus in patients with AIDS," *Science* 220(1983): 859-862.
2. E. P. Gelmann, M. Povovic, D. Blayney, H. Masur, G. Sidhu, R. E. Stahl, and R. C. Gallo, "Proviral DNA of a retrovirus, human T-cell leukemia virus, in two patients with AIDS," *Science* 220(1983): 0862-865; R. C. Gallo, P. S. Sarin, E. P. Gelmann, M. Robert-Guroff, E. Richardson, V. S. Kalyanaraman, D. Mann, G. D. Sidhu, R. E. Stahl, S. Zolla-Pazner, J. Leibowitch, and M. Popovic, "Isolation of human T-cell leukemia virus in acquired immune deficiency syndrome," *Science* 220(1983): 865-867.
3. F. Barré-Sinoussi, J. C. Chermann, F. Rey, M. T. Nugeyre, S. Chamaret, J. Gruest, C. Dauguet, C. Axler-Blin, F. Brun-Vézinet, C. Rouzioux, W. Rozenbaum, and L. Montagnier, "Isolation of a T-lymphotropic retrovirus from a patient at risk for acquired immune deficiency syndrome (AIDS)," *Science* 220(1983): 868-871.
4. L. Montagnier, J. C. Chermann, F. Barré-Sinoussi, S. Chamaret, J. Gruest, M. T. Nugeyre, F. Rey, C. Dauguet, C. Axler-Blin, F. Vézinet-Brun, C. Rouzioux, G. A. Saimot, W. Rozenbaum, J. C. Gluckman, D. Klatzmann, E. Vilmer, C. Griscelli, C. Foyer-Gazengel, and J. P. Brunet, "A new human T-lymphotropic retrovirus: characterization and possible role in lymphadenopathy and acquired immune deficiency syndrome," in R. C. Gallo, M. E. Essex, and L. Gross, eds., *Human T-Cell Leukemia/Lymphoma Virus. The Family of Human T-Lymphotropic Retroviruses: Their Role in Malignancies and Association with AIDS* (Cold Spring Harbor, New York: Cold Spring Harbor Laboratory, 1984), 363-379.
5. M. Popovic, M. G. Sarngadharan, E. Read, and R. C. Gallo, "Detection, isolation, and continuous production of cytopathic retroviruses (HTLV-III) from patients with AIDS and pre-AIDS," *Science* 224(1984): 497-500; R. C. Gallo, S. Z. Salahuddin, M. Popovic, G. M. Shearer, M. Kaplan, B. F. Haynes, T. J. Palker, R. Redfield, J. Oleske, B. Safai, G. White, P. Foster, and P. D. Markham, "Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS," *Science* 224(1984): 500-503; J. Schüpbach, M. Popovic, R. V. Gilden, M. A. Gonda, M. G. Sarngadharan, and R. C. Gallo, "Serological analysis of a subgroup of human T-lymphotropic retroviruses (HTLV-III) associated with AIDS," *Science* 224(1984): 503-505; M. G. Sarngadharan, M. Popovic, L. Bruch, J. Schüpbach, and R. C. Gallo, "Antibodies reactive with human T-lymphotropic retroviruses (HTLV-III) in the serum of patients with AIDS," *Science* 224(1984): 506-508.
6. *Science* was at a very early stage of computerization. Reviewers' names were put into a computer database in the mid-1970s, but few editors used it, it was seldom updated, and it was soon abandoned. A

new computer system took its place in about 1981, but it was used mainly for manuscript tracking. Editors did not have computers at their desks until 1985.

7. Records for the AIDS papers received in the early 1980s were filed not under AIDS, but according to the main focus of the paper, such as cytomegalovirus (CMV) or tumor biology for papers on Kaposi's sarcoma; general immunology for papers on excessive antigenic stimulation; rickettsia or mycoplasma for papers proposing these organisms as etiological agents.
8. R. Kulstad, "Reports in *Science* and the concern about quality," unpublished manuscript, April 1983.
9. N. Hartnagle, "Reorganized *Science* editorial office," unpublished manuscript, November 1982.
10. The *AIDS Memorandum*, prepared and distributed by the National Institute of Allergy and Infectious Diseases, served "as a forum for the rapid exchange of new information and ideas among clinicians and scientists involved in AIDS research and management." Copies are available in the manuscript collection, National Library of Medicine.
11. E. M. Lord, G. F. Sensabaugh, and D. P. Stites, "Immunosuppressive activity of human seminal plasma. I. Inhibition of in vitro lymphocyte activation," *Journal of Immunology* 118(1977): 1704-1711; D. A. Anderson and T. H. Tarter, "Immunosuppressive effects of mouse seminal plasma components in vivo and in vitro," ibid. 128(1982): 535-539.
12. See comments on CDC/NIH/FDA Meeting, March 1982, made by D. P. Francis, in his "The search for a cause," in K. M. Kahill, ed., *The AIDS Epidemic* (New York: St. Martin's Press, 1983), (preprint).
13. W. P. Carney, W. H. Rubin, R. A. Hoffman, W. P. Hansen, K. Healey, and M. S. Hirsch, "Analysis of T lymphocyte subsets in cytomegalovirus mononucleosis," *Journal of Immunology* 126(1981): 2114-2116; Y. Becker, "The Epstein-Barr virus and human cancer," in G. Giraldo and E. Beth, eds., *The Role of Viruses in Human Cancer*, vol. 1, Proceedings of the First International Congress of Viral Oncology, Naples, Italy, 1979 (New York: Elsevier, 1980), 7-27. This multifactorial etiology for AIDS was also fueled by the finding, reported in October 1983, that KS cells could harbor both CMV and EBV simultaneously. See G. V. Quinnan, G. Armstrong, G. Pearson, A. Rook, R. Steis, P. Leming, J. Ames, and H. Masur, book of abstracts for meeting, "23rd Interscience Conference on Antimicrobial Agents and Chemotherapy," Las Vegas, October 1983, Abstr. 964, 261.
14. In the first issue of the journal *AIDS Research* (Mary Ann Liebert, Inc., Publishers, vol. 1, no. 1, 1983), the editor, J. A. Sonnabend, himself a proponent of "an alternative hypothesis regarding the genesis of AIDS," included several papers suggesting that there was "no specific etiologic agent of AIDS."
15. J. M. Richards, J. M. Bedford, and S. S. Witkin, "Rectal insemination modifies immune responses in rabbits," *Science* 224(1984): 390-392.
16. See notes 1, 2, and 3.
17. S. Odend'hal, *The Geographical Distribution of Animal Viral Diseases* (San Diego, California: Academic Press, 1983), 121-122. Canine parvovirus is a small, autonomous, DNA virus related to defective adeno-associated viruses of various species. Antibodies to autonomous and defective parvoviruses have been detected in humans, and the viruses have been implicated in some human diseases (see also note 25; this finding, to my knowlege, was not confirmed in later work).
18. See meeting notes and abstracts distributed at the symposium in: Rickettsial diseases symposium in honor of Miodrag Ristic, organized by the American Society of Tropical Medicine and Hygiene in conjunction with the American Society of Tropical Veterinary Medicine, Washington, D.C., 7 December 1988 (unpublished).
19. Potomac horse fever was renamed equine monocytic ehrlichiosis after the causative agent, subsequently named *Ehrlichia risticii*, was isolated in 1984 (C. J. Holland, M. Ristic et al., "Isolation, experimental transmission, and characterization of the causative agent of Potomac horse fever," *Science* 227(1985): 522-524). Two other new members of the Rickettsiaceae were discovered recently: *Ehrlichia chaffeensis*, which was identified as the cause of human ehrlichiosis in 1991 (B. E. Anderson et al., "*Ehrlichia chaffeensis* a new species associated with human ehrlichiosis," *Journal of Clinical Microbiology* 29(1991): 2838-2842), and *Rochalimaea henselae*, which was first found to be associated with bacillary angiomatosis (D. A. Relman et al., "The agent of bacillary angiomatosis: an approach to the identification of uncultured pathogens," *New England Journal of Medicine* 323(1990): 1573-1580; L. N. Slater et al., " A newly recognized fastidious gram-negative pathogen as a cause of fever and bacteremia," ibid. 323(1990): 1587-1593), and was later identified as also being involved with some cases of HIV encephalopathy (M. Patnaik et al., "Possible role of *Rochalimaea henselae* in pathogenesis of AIDS encephalopathy," *Lancet* 340(1992): 972).
20. Other good sources of reviewers were symposium volumes found in the *Science* Book Reviews depart-

ment. Such volumes included those of the *UCLA Symposia on Cellular and Molecular Biology*, those from the Cold Spring Harbor Laboratory, and the *Progress in Medical Virology* series (published by Karger). *Science* lacked an extensive library and the editors rarely went to meetings in the early 1980s; published meeting proceedings were therefore valuable not only for finding reviewers, but for keeping informed on progress in different areas of science.

21. The tried and trusted reviewers were sometimes asked to act as anonymous referees to evaluate two or more conflicting reviews or settle disputes between authors and their reviewers.
22. That the *Science* peer-reviewing system had a good reputation might be considered substantiated by the fact that authors in several fields submitted their papers to *Science* knowing that they were unlikely to be accepted but in order to receive the benefits of constructive criticism. They knew that their papers would probably be seen by two good people in their field, and, in the event they were looking for a new position or seeking a grant, favorable comments could be helpful.
23. E.g., R. F. Doolittle, M. W. Hunkapiller, L. E. Hood, S. G. DeVare, K. C. Robbins, S. A. Aaronson, and H. N. Antoniades, "Simian sarcoma virus onc gene, v-sis, is derived from the gene (or genes) encoding a platelet-derived growth factor," *Science* 221(1983): 275-277.
24. E.g., D. J. Slamon, J. B. deKernion, I. M. Verma, and M. J. Cline, "Expression of cellular oncogenes in human malignancies," *Science* 224(1984): 256-262.
25. E.g., R. W. Simpson, L. McGinty, L. Simon, C. A. Smith, C. W. Godzeski, and R. J. Boyd, "Association of parvoviruses with rheumatoid arthritis of humans," *Science* 223(1984): 1425-1428.
26. The paper by Kary Mullis that was turned down by *Science* and *Nature* in 1985 and published in 1987 in *Methods in Enzymology* (K. B. Mullis and F. A. Faloona, "Specific synthesis of DNA in vitro via a polymerase-catalyzed chain reaction," *Methods in Enzymology* 155[1987]: 335-350) gave a description of the method but no demonstration of the application of PCR to a particular problem. Another paper from Mullis and his colleagues, demonstrating the diagnostic capability of PCR, was accepted by *Science* in 1985: R. K. Saiki, S. Scharf, F. Faloona, K. B. Mullis, G. T. Horn, H. A. Erlich, and N. Arnheim, "Enzymatic amplification of beta-globin genomic sequences and restriction site analysis for diagnosis of sickle cell anemia," *Science* 230(1985): 1350-1354.
27. For papers where readers might think of the work as being immediately applicable to medical conditions, it was editorial policy to add notes of caution about the preliminary nature of the findings and the need for further studies before they could be applied to humans.
28. See notes 1, 2, and 3.
29. See note 2.
30. See note 2.
31. See note 1.
32. See note 1.
33. Murphy was in charge of the proofreaders and the layout and art departments. She dealt directly with the printer and was responsible for the journal coming off the press on time (by late Thursday) 51 weeks of the year. The pressures of the job allowed her little time to dwell on the content of the papers being published, and it was up to the editors to keep her informed about hot papers and to negotiate publication dates.
34. See note 3.
35. M. Essex, M. F. McLane, T. H. Lee, N. Tachibana, J. I. Mullins, J. Kreiss, C. K. Kasper, M. C. Poon, A. Landay, S. F. Stein, D. P. Francis, C. Cabradilla, D. N. Lawrence, and B. L. Evatt, "Antibodies to human T-cell leukemia virus membrane antigens (HTLV-MA) in hemophiliacs," *Science* 221(1983): 1061-1064.
36. In cats infected with FeLV and humans infected with HBV there is a prolonged latent period before the development of malignancy. Essex et al. pointed out that although HBV is a DNA virus and targets liver rather than lymphoid tissue, the development in cats of virus-negative lymphoid malignancies that are clearly linked to FeLV infection suggests that a similar phenomenon, i.e., of virus-negative, HBV-induced tumor tissue, should not be unexpected with respect to PHC. A connection between HBV infection and PHC had long been suspected by some HBV researchers, but the inability to demonstrate the presence of viral sequences in hepatic tumor tissue left many others unconvinced. See M. Essex and N. A. Gutensohn, "A comparison of the pathobiology and epidemiology of cancers associated with viruses in humans and animals," 114-126, and D. P. Francis, M. Essex, and J. E. Maynard, "Feline leukemia virus and hepatitis B virus: a comparison of late manifestations," 127-132, in P. Maupas and J. L. Melnick, eds. *Hepatitis B Virus and Primary Hepatocellular Carcinoma*, Workshop held at the Faculty of Medicine, Dakar,

Senegal, April 21-24, 1980 (Basel, Switzerland: Karger, 1981), vol. 27 of *Progress in Medical Virology*, J. L. Melnick, Series Editor.

37. H. W. Jaffe, D. P. Francis, M. F. McLane, C. Cabradilla, J. W. Curran, B. W. Kilbourne, D. N. Lawrence, H. W. Haverkos, T. J. Spira, R. Y. Dodd, J. Gold, D. Armstrong, A. Ley, J. Groopman, J. Mullins, T. H. Lee, and M. Essex, "Transfusion-associated AIDS: serologic evidence of human T-cell leukemia virus infection of donors," *Science* 223(1984): 1309-1312.
38. Other journals were also publishing reports of probable AIDS transmission through blood transfusion in this period. See, for example, "Leads from *MMWR* (32[8][1983], Centers for Disease Control, Atlanta). Prevention of acquired immune deficiency syndrome (AIDS): Report of inter-agency recommendations," in *JAMA* 249(1983): 1544-1545; J. W. Curran, D. N. Lawrence, H. Jaffe, et al., "Acquired immunodeficiency syndrome (AIDS) associated with transfusions," *New England Journal of Medicine* 310(1984): 69-75.
39. One might view *Science* as being used, on occasion, for political or for industrial advantage. For examples, see papers published in the late 1970s on radioactivity in the Ural Mountains and on nuclear power generation. In the era of biotechnology, one might also interpret the efforts (and sometimes the success) of biotechnology companies to publish papers in *Science* as efforts to use the journal for company gain.
40. See, for example, M. D. Daniel, N. W. King, N. L. Letvin, R. D. Hunt, P. K. Sehgal, and R. C. Desrosiers, "A new type D retrovirus isolated from macaques with an immunodeficiency syndrome," *Science* 223(1984): 602-605; K. Stromberg, R. E. Benveniste, R. O. Arthur, H. Rabin, W. E. Giddens, Jr., H. D. Ochs, W. R. Morton, and C. C. Tsai, "Characterization of exogenous type D retrovirus from a fibroma of a macaque with simian AIDS and fibromatosis," *Science* 224(1984): 289-292.
41. M. D. Daniel, N. L. Letvin, N. W. King, M. Kannagi, P. K. Sehgal, R. D. Hunt, P. J. Kanki, M. Essex, and R. C. Desrosiers, "Isolation of T-cell tropic HTLV-III-like retrovirus from macaques," *Science* 228(1985): 1201-1204.
42. See note 5.
43. A. S. Relman, *Introduction to AIDS: The Emerging Ethical Dilemmas*, *Hastings Center Report* Special Supplement, August 1985 (Hastings-on-Hudson, New York: Hastings Center, 1985).
44. P. M. Feorino, V. S. Kalyanaraman, H. W. Haverkos, C. D. Cabradilla, D. T. Warfield, H. W. Jaffe, A. K. Harrison, M. S. Gottlieb, D. Goldfinger, J. C. Chermann, F. Barré-Sinoussi, T. J. Spira, J. S. McDougal, J. W. Curran, L. Montagnier, F. A. Murphy, and D. P. Francis, "Lymphadenopathy associated virus infection of a blood donor-recipient pair with acquired immunodeficiency syndrome," *Science* 225(1984): 69-72; D. Klatzmann, F. Barré-Sinoussi, M. T. Nugeyre, C. Dauguet, E. Vilmer, C. Griscelli, F. Brun-Vézinet, C. Rouzioux, J. C. Gluckman, J. C. Chermann, and L. Montagnier, "Selective tropism of lymphadenopathy-associated virus (LAV) for helper-inducer T lymphocytes," *Science* 225(1984): 59-63; V. S. Kalyanaraman, C. D. Cabradilla, J. P. Getchell, R. Narayanan, E. H. Braff, J. C. Chermann, F. Barré-Sinoussi, L. Montagnier, T. J. Spira, J. Kaplan, D. Fishbein, H. W. Jaffe, J. W. Curran, and D. P. Francis, "Antibodies to the core protein of lymphadenopathy-associated virus (LAV) in patients with AIDS," *Science* 225(1984): 321-323; L. Montagnier, J. Gruest, S. Chamaret, C. Dauguet, C. Axler, C. Guétard, M. T. Nugeyre, F. Barré-Sinoussi, J. B. Brunet, J. C. Chermann, D. Klatzmann, and J. C. Gluckman, "Adaptation for lymphadenopathy-associated virus (LAV) to replication in EBV-transformed B lymphoblastoid cell lines," *Science* 225(1984): 63-66.
45. J. A. Levy, A. D. Hoffman, S. M. Kramer, J. A. Landis, J. M. Shimabukuro, L. S. Oshiro, "Isolation of lymphocytopathic retroviruses from San Francisco patients with AIDS," *Science* 225(1984): 840-842.
46. L. A. Valleroy, "The AIDS epidemic and the 100th Congress of the United States: politics and public health policy," in R. Kulstad, ed., *AIDS 1988: AAAS Symposia Papers* (Washington, D.C.: AAAS, 1988), 315-321.
47. M. A. Gonda, F. Wong-Staal, R. C. Gallo, J. E. Clements, O. Narayan, R. V. Giden, "Sequence homology and morphologic similarity of HTLV-III and visna virus, a pathogenic lentivirus," *Science* 227(1985): 173-177.
48. M. Mitsuya, M. Popovic, R. Yarchoan, S. Matsushita, R. C. Gallo, and S. Broder, "Suramin protection of T cells in vitro against infectivity and cytopathic effect of HTLV-III," *Science* 226(1984): 172-174.
49. K. J. Lui, D. N. Lawrence, W. M. Morgan, T. A. Peterman, S. Haverkos, and D. Bregun, "A model-based approach for estimating the mean incubation period of transfusion-associated acquired immune deficiency syndrome," *Proceedings of the National Academy of Sciences, U.S.A.* 83(1986): 3051-3055.
50. C. A. Rosen, J. G. Sodroski, and W. A. Haseltine, "The location of cis-acting regulatory sequences in the human T cell lymphotropic virus type III (HTLV/LAV) long terminal repeat," *Cell* 41(1985): 813-823.

AIDS: From Public History to Public Policy

Allan M. Brandt

It has become something of a truism in the age of AIDS to cite the aphorism of philosopher George Santayana that "those who do not remember the past are condemned to repeat it." No doubt much about AIDS reminds us of past epidemics we would like to avoid repeating. The implication of Santayana's statement is, of course, that those who remember the past are not condemned to repeat it. But now, as we pause to consider the history of AIDS, I am increasingly impressed that those who remember the past may be condemned to repeat it anyway. Or perhaps historians are condemned to realize that we are repeating the past. AIDS reminds us that epidemic disease has typically been fraught with fears of contagion, stigmatization of victims, conflicts between public and civil liberties, and a traditional cultural ambivalence regarding sexuality. Although a strong historical sensibility may deepen our understanding of the AIDS epidemic, it is unlikely to contribute in any immediate sense to better public policy. Nonetheless, rigorous historical inquiry and analysis might illuminate the policy debate—demonstrating the full range of scientific, cultural, and political forces that have shaped policy considerations in the epidemic.

Rather than historians affecting the epidemic, significantly, the epidemic has had a powerful effect on studies in the history of medicine. AIDS has forced historians to reevaluate a whole series of questions about the scientific, biomedical, social, and cultural responses to disease in both the past and the present. AIDS has already influenced the course of American medical historiography in at least three important ways. First, AIDS has encouraged new interest in and analysis of epidemic disease in the past. The epidemic has generated a new (or at least altered) set of questions about historical responses to earlier epidemic diseases. Questions have arisen, for example, relating to physicians' responsibility in times of epidemics,[1] notions of risk-taking and risk aversion,[2] the nature of voluntarism, experimentalism,[3] the role of the state as it relates to public health and individual liberties.[4] The crucial boundaries between public and private life have become an important analytic focus. Although these issues are in some ways familiar, they have been recast in the age of AIDS.

Second, the epidemic has reemphasized the significance of historical studies of the nature and process of public policy as it relates to disease. This, of course, is not to argue that historians have special claims or particular skills in adjudicating conflicts regarding policy initiatives in times of epidemics, but rather that their studies may illuminate the range of options and, more important, the nature of the multifarious forces that promote or inhibit effective public policies. Few would argue that history has no significance for the world of policy-making; more complex is to define the role that historians might undertake in this endeavor. Recent work on the history of public policy suggests that historians may be able to demonstrate how certain fundamental policy options are related to a variety of political and cultural forces that need to be brought into consideration.[5] AIDS

has forced a fuller recognition of the dimensions of health policy as it relates to such questions as civil liberties and the state; public health and the delivery of services; policies at the hospital and local level; and, significantly, the relationship of health policy to scientific knowledge, a critical issue virtually ignored in many earlier studies.

Third, the epidemic has reminded medical historians—as it has American culture more generally—of the visceral, cutting nature of epidemics. The AIDS epidemic provides a sad but powerful reminder of our relative inability, in spite of a remarkable knowledge and technology, to shape rationally and effectively the nature of our world.[6] It delineates both the strengths and weaknesses of the biomedical model of disease with its powerful emphasis on "specificity" of cause and treatment. Moreover, the first decade of the epidemic provides something of an antidote to Whiggish historical assumptions regarding progress, rationality, and change. AIDS has reminded historians of the deeper relationships of patterns of disease to enduring social structures, relationships, and economic conditions.

Although historians of medicine had begun to focus on disease itself as the critical unit of analysis even before AIDS, the epidemic has accelerated this historiographic trend. Historical assessment of AIDS has focused on a basic premise: that the way a society *responds* to problems of disease will reveal its deepest values. That disease is not merely biological—it is shaped by a wide range of behavioral, social, cultural, and political forces. Typically, historians have studied the history of disease not because such investigation would guide policy, but rather because the study of disease—and social responses to disease—tells us *about* society—in the past—and in the present.

Nonetheless, it now seems clear that a sophisticated understanding of disease meanings may have significant implications for public policy. Historical investigation of AIDS moves us from public history to public policy. To argue that AIDS is "socially constructed" seems commonplace at this stage of the epidemic. Few would question the fact that powerful social, cultural, and political forces have shaped the meaning of AIDS. And few would dispute that these meanings have, in turn, had a fundamental impact not only on public policies relating to AIDS, but also on the material biological and epidemiologic course of the epidemic. Furthermore, it now has become clear that there is no single meaning of AIDS. Rather than a "social construction" of the epidemic, there are—at any given moment in time—a series of constructions competing for cultural and political dominance.[7] These contests for meaning have dramatic implications for the direction that public policies shall take. Among the questions embedded in the social meanings of AIDS are debates about what are the nature of the risks of HIV; who is at risk; and how should we—as a society and a polity—respond to these risks.

The battles over the meaning of AIDS, fought both overtly or covertly, have often been reflected in the language and terminology of the epidemic. Take, for example, the frequently used expression "innocent victims" of AIDS, employed typically to refer to those who acquired their infections through blood transfusions, perinatally, or in the extremely rare case, through a medical interaction. The term "innocent victims" set this group of HIV-infected individuals apart from those who have been at highest risk of acquiring HIV, namely gay men and intravenous drug users. The subtle implication has been that these groups are not "innocent"; indeed, the ultimate implication is that these groups are "guilty"—the perpetrators of a lethal infection.[8] In another example, concern was voiced about the term "risk groups" as opposed to risk behaviors. "Risk groups," it was suggested, presented opportunities for stigmatization.[9] The term "AIDS victims," I learned at a very early meeting on the epidemic when I used the term, was offensive to persons with AIDS because it was viewed as being disempowering. Questions about the shift from discussing sexual "preference" to sexual "ori-

entation"—a shift that has occurred during the course of the epidemic—reflect subtle but powerful recognitions of assumptions about agency in relation to behavior.[10]

These concerns about language were not simply debates in semantics—they had real political importance, in influencing both cultural perceptions and public policy. Deciphering the meanings of disease, then, serves a number of functions, from the general goals of humanistic inquiry; to the preservation of a record of our times; to the actual shaping of public responses. If the meaning of AIDS is a critical factor in determining public policy, then inquiry into the process of how AIDS meanings are formed and reformed, constructed and reconstructed, may offer some insight in the formulation of public policy.

As many have noted, the pendulum of AIDS has swung since the inception of the epidemic between irrational fears that often bordered on hysteria, to a complacency and denial that bred neglect. Historians analyzing this phenomena will, in all likelihood, look at certain debates as representative of the problem of creating effective and humane public policies. Fears that AIDS would "leach" from groups identified as being at high risk, (namely, homosexual males and intravenous drug users) to the so-called "general population" led to angry demands for mandatory screening and identification (witness William F. Buckley's call for tattooed buttocks); claims for detention and quarantine sometimes followed. Some may remember a PBS Frontline documentary on the epidemic that aired in 1988 that stirred fears of HIV-infected male prostitutes wantonly spreading infection. In Boston, some surgeons talked of the possibility of using the harbor islands—where smallpox patients had been isolated in the nineteenth century—to detain HIV-infected individuals. Sex researchers, William Masters and Virginia Johnson, fanned the flames of anxiety in their 1988 book, *Crisis*;[11] by projecting a massive heterosexual epidemic that they claimed was being spread by the singles-bar morality of the 1970s and 1980s. Legislatures debated, and in some instances passed, requirements for premarital serologies for HIV—in spite of counsel from public health experts demonstrating the ineffectiveness of such programs.[12] During these years, 1983 to 1990, fears of casual transmission ran high, as did concern about other vectors for transmission of the virus.[13] In this context, the greatest victories in AIDS public policy during the first decade of the epidemic centered on preventing Draconian and ineffective measures, rather than in promoting a proactive, positive set of public health interventions.

In the battle for the meaning of the epidemic, however, some critics began to aggressively ask what all the fuss was about. AIDS, they argued, was "confined" to those with clear risks. According to this argument, perhaps most explicitly articulated in Michael Fumento's *The Myth of Heterosexual AIDS*,[14] a zealous liberal/gay lobby had secured support for AIDS research and prevention far beyond the epidemic's "real" effect and dangers. Gary Bauer, a Reagan domestic advisor, championed this view in the White House. During the Reagan years it was difficult to get the President to utter the word "AIDS," let alone establish a coherent national policy. As Surgeon General C. Everett Koop notes in this volume, the epidemic, because of its particular meanings and politics, was anathema in the White House.

As the first decade of the epidemic came to an end, the perception of AIDS as being principally limited to those at high risk led to increasing complacency about the epidemic. Calls for quarantine and isolation diminished. Increasingly, a perception of a "social" quarantine arose. According to this construction, the epidemic was confined to those who transgressed by taking unnecessary sexual risks, or using illegal substances. Attention typically was galvanized by those instances in which those perceived to be at high risk spread their infections to those otherwise considered to be risk-free (or at least outside of the principal "risk-groups")—instances in which the "metaphorical" quarantine was breached. This explains, in part, the intense debates about hospital infections—patients and providers now came

together in an atmosphere of fear and loathing—bringing new suspicion and bitterness to their encounters. Symbolic actors—seized upon by the press—stirred these enmities. Dr. Lorraine Day, an orthopedic surgeon at the University of California San Francisco, became an overnight media sensation. She lectured widely showing scenes of orthopedic carnage in her operating room, while demanding the "right to know" the HIV status of her patients, as well as the right to refuse them treatment. On the other side of this conflict stood the tragic figure of Kimberly Bergalis, soon to be pictured wasting on the cover of *People Magazine*.[15] To have followed press accounts in the late 1980s and early 1990s, one might well have assumed that hospitals and dentists' offices were the *principal* loci in which HIV was spread.[16] This, despite the epidemiologic reality that these institutions were remarkably safe, at least so far as AIDS transmission was concerned.

These concerns about transmission of the virus resonated powerfully with earlier epidemics of sexually transmitted infections in which the terminology of "syphilis of the innocent" or "venereal diseases of the innocent" was also prominent. The idea of dividing individuals who became infected into two groups now became a prominent aspect of HIV. Early in the epidemic, a journalist wrote in the *New York Times Magazine*: "The groups most recently found to be at risk for AIDS present a particularly poignant problem. Innocent bystanders, caught in the path of a new disease, they can make no behavioral decisions to minimize their risks: hemophiliacs can not stop taking blood clotting medication, surgery patients can not stop getting transfusions, women can not control the drug habits of their mates, babies can not choose their mothers."[17] Further, to suggest that it was a "particularly poignant problem," when for example, a woman or a baby became HIV infected, implied that it was somehow less poignant when those who were at highest risk of becoming infected had actually succumbed. These so-called "innocent infections" served the purpose of reifying notions of responsibility and guilt for the epidemic itself. As both Day and Bergalis had argued, there were *perpetrators* of the disease and innocent "victims." Innocent infections were the unusual but critical *exceptions*—that proved the rule—affirming notions of rationality and responsibility for the epidemic. Of course, it is not unusual in times of epidemic to attempt to develop means of adjudicating responsibility for risk to self and others. But in the specific context of HIV, these assessments reflected historically specific cultural and political forces.

In a pluralistic and diverse culture, epidemic disease offers significant possibilities for fear to become hatred and anxiety to become rage. Rather than asking what causes AIDS (as many scientists at the National Institutes of Health and elsewhere have asked) the basic cultural query has typically been "Who causes AIDS?" This explains, in part, the significance attached to testing throughout the epidemic. The attempts to mandate testing reflect a powerful historical desire to find rationality in instances of epidemic disease, to assert control and order over the powerful and intense uncertainties engendered by epidemics. The distorted constructions of AIDS—from Masters and Johnson to Fumento—created a context in which inventive and successful approaches to the epidemic were likely to be blocked. The hysteria associated with claims for a massive heterosexual epidemic, or the denial associated with the so-called "myth" of heterosexual AIDS, offered few possibilities for rational or effective policy-making.

In the context of these particular meanings of the disease, programs for education and prevention, which most observers had identified as the best hope for mitigating the epidemic, typically languished or failed to be adequately implemented. If one looks, for example, at the reports of the National Commission on AIDS or the earlier Presidential Commission on AIDS, any number of appropriate and perhaps effective interventions including wider dis-

tribution of condoms, the idea of needle exchange, or drug treatment on demand were proposed but all have met signficant opposition. Survey research on American sexual behaviors and practices, crucial to the development of effective public health education, was blocked during the Bush Administration. More than a decade into the epidemic, the Kinsey Reports remained widely cited as the best data available on sexual behaviors and practices. This despite the fact that the surveys from which Kinsey drew his conclusions were now well over thirty years old.

The conflicts about educational and behavioral approaches to addressing AIDS reflect importantly on the historical and cultural meanings of the epidemic, especially notions of individual responsibility and personal agency that run deep in our health values. "Just say no" explicitly invokes a powerful American sensibility about risk, behavior, and disease. Seeing "at risk" individuals as both responsible for their own infections *and* the epidemic seems ultimately to be the principal explanation for the lack of any substantive, targeted educational and preventive programs. Such programs would contextualize risk and recognize how highly differentiated risk can be for peoples in our culture.

All during the first decade of the epidemic the absence of leadership—as both Dr. June Osborn and Dr. C. Everett Koop have made clear in their articles in this volume—was haunting. The notion that no one was home at the White House seemed ever more apparent by the mid-1980s. One argument, of course, was that President Reagan's constituencies, especially conservative fundamentalists, served to block any action against AIDS.[18] Yet from a "purely" political point of view AIDS leadership might have had significant political appeal.

Let me present what historians sometimes call a "counterfactual hypothesis." In Florida in 1986, when the Ray family's home was burned down because their three sons, who were hemophiliacs, were HIV positive, consider what would have happened if President Reagan had gone on national television that evening. He could have had Nancy sitting in a chair by his side, looking up at him, and he could have said "What happened in Florida this week was a horrible tragedy. From now on this family will live with Nancy and me in the White House until we find appropriate housing for them. We must begin to recognize the problems raised by this epidemic, and how to address them compassionately." Such a statement might have had an impact on the epidemic. It would not have been a commitment of resources to the epidemic. Nonetheless, acts of leadership, essentially symbolic acts, could have changed the meanings of the epidemic in important ways. We will never know what could have happened, and, of course, that is the problem with counterfactual hypotheses.[19]

Nonetheless, the coincidence of the twelve years of the Reagan and Bush administrations and the rapid emergence of AIDS during this period is unlikely to be overlooked by historians of the epidemic.

If the question that generated attention and debate during the first decade of the epidemic was "*How* do we see AIDS?" the question today is "*Do* we see AIDS?" Over the last several years we have witnessed a process in which the epidemic has come to be *routinized.* The AIDS crisis, which grabbed public attention and stirred debate during its first decade, has become in the public culture simply "AIDS," one of a number of difficult, if not intractable, social problems incorporated into the polity. AIDS has become mundane.[20] Obviously some aspects of this process of routinization may be functional. AIDS has generated courses in our schools, textbooks, and journals. Clinical research has helped to identify appropriate standards of care. Institutional clinical experience has served to reduce the discrimination and stigma that so often accompanied the disease in the first decade of the epidemic. In other ways, however, this process of routinization has moved AIDS from spotlight to shadow. Calling AIDS a chronic disease, for example, as some historians have,

obscures the dynamic aspects of its transmissible and infectious character.[21] Although the attribution of chronicity may well have given some patients hope, it grouped AIDS with a set of diseases unlikely to attract attention and resources, and placed AIDS among a set of diseases which our health care system has traditionally handled poorly. To call an infectious disease "chronic," can only be understood as one aspect of the contest for meanings in the epidemic, and was one aspect in the process of making AIDS routine. What, one might ask, is "chronic" about a disease that principally kills young people?

Ultimately this process of routinization has critical policy implications for the epidemic. Routinization has the effect of distancing the public from the suffering inherent in the epidemic. This act of social dissociation, the idea that AIDS is mundane, further marginalizes those who are ill. We move, slowly, from thinking in time—"crisis" thinking—which is required in times of epidemic, to "problem" thinking. With routinization, the urgency of the epidemic has been significantly diminished.

Epidemics are moving targets. In this sense many of our public policy processes are poorly designed to construct and implement effective interventions.[22] In this respect, one might consider, for example, the debate about the provision of sterile needles to intravenous drug users. There is now growing support in a number of American cities for the idea that sterile needles might be an effective public health approach to reducing the transmission of HIV among intravenous drug users. Yet, during the years in which this intervention was debated, many intravenous drug users became HIV positive, and the potential benefits of the program were compromised in the course of a slow and often angry debate.

While such policies have lagged, the epidemic has become endemic, especially in American inner cities, among intravenous drug users, and minority populations. It was this process of losing sight of the epidemic that led to the recent National Research Council report on monitoring the social impact of AIDS (which I participated in writing).[23] Our committee found that AIDS was not generating the types of social responses we anticipated, nor was it having a sustained impact on American institutions. A letter from a colleague on the committee, written during our deliberations, characterizes a central theme that emerged in the ultimate report:

> The list of topics we chose suggested the institutional range of severe impacts that we expected: health care, volunteerism, intimate relations in the family, the criminal justice system, religion, public health. My sense (when the panel began its work) was that the impacts would be severe and long lasting in many areas of social life and that the United States would be a somewhat different kind of place as a result of the epidemic. I no longer believe this to be so and the remainder of this memo should suggest why. Let me give you my general conclusion first: I now believe that. . . [in] a large, complex and affluent society, in which the important social actors are large scale organizations and in which the mass media occupies a special place for managing social reality, that it will be possible to tolerate the excess deaths of about one million or so persons over a period of twenty years without any "nation level" social changes. It had become clear that the epidemic has been successfully defined as a conventional medical problem by all levels of the health care system. Secondarily, it became apparent that the costs of the epidemic on the national level could be handled, even though severe but temporary local dislocations might occur in areas most heavily impacted by ill persons. Federal assistance to

> these disaster areas was substantially cut in the recent budget, but I would expect some levels of funding that would allow localities to limp along until the majority of those infected die (perhaps by the early years of the twenty-first century). Outside of the most heavily impacted locales (and here I mean neighborhoods, not cities) and in the absence of a major outbreak of disease among the currently uninfected, it is my view that AIDS will be treated an as "affordable epidemic" which involves "tolerable levels of wastage." My primary reason for making this argument rests upon the fact that the persons who have been primarily impacted by the epidemic come from socially marginalized groups whose "loss" to the society can easily be tolerated by those not immediately affected. The fact that gay men, intravenous drug users, African and Latino-Americans, the women sexual partners of drug users and the children of these women represent the current and future majority of those infected (and there is no good current evidence to the contrary) means that their sickness and deaths are tolerable. (Not by everybody, but surely tolerable by the many and the powerful). At this moment our society tolerates drug use, infant mortality, tuberculosis, imprisonment, unemployment, unwanted pregnancy, dangerous schools and housing as the normal conditions of many poor people and ethnic minorities—there is no reason why we, as a society, should not tolerate illness and death in these populations from other sources.[24]

This sad and sober view of the epidemic has, of course, been contested as well. Some have argued that to identify the marginalization of AIDS is to encourage its further marginalization. There are questions of whether the risks of AIDS should be portrayed as universal or as highly differentiated. Many read the National Research Council report, much to the committee's surprise and dismay, as saying that AIDS was no longer a problem.[25]

This critical view of the policy context of the epidemic gives short shrift to the remarkable acts of valor and courage that have also been present. The impressive history of activism and advocacy in the context of AIDS has fundamentally changed the calculus of health politics. The brilliant and committed work of scientists, the courageous work of the National AIDS Commission that served as the conscience of a timorous government, the individual acts of heroism among healers and public health officials who have dedicated themselves to patients and populations in need, contrast sharply with the failures of public policy.

We stand at a critical crossroads in the epidemic. As the epidemic intensifies here and abroad—the World Health Organization currently estimates twenty million people to be HIV-positive—gathering the attention, resources, and commitment required to fight it seems ever more difficult. Only a sophisticated understanding of the social meanings of AIDS and the process by which they achieve attention and legitimacy offers potential pathways to a just public policy. This is a role in which historians may make a modest but important contribution. If the meanings of the epidemic are malleable and contingent, then it is necessary to give greater attention to working explicitly to shape them. A generation from now, historians may look back at the AIDS epidemic proud of our capacity forthrightly and humanely to address a profound human crisis, or they may look back and mark this disease as a crisis that fundamentally exacerbated the bitterest divisions of our world. Only when we recognize the significance of social and cultural values in constructing disease will we be able to develop the effective, humane, and just social responses this epidemic demands.

Notes

1. See, for example, A. Zuger and S. H. Miles, "Physicians, AIDS, and occupational risk: historic traditions and ethical obligations," *Journal of the American Medical Association* 258(14)(1987): 1924-1928.
2. See Edward J. Burger Jr., ed., *Risk* (Ann Arbor: University of Michigan Press, 1990, 1993).
3. George J. Annas, "The changing landscape of human experimentation: Nuremberg, Helsinki, and beyond," *Health Matrix* 2(2)(1992): 119-140.
4. Ronald Bayer, *Private Acts, Social Consequences: AIDS and the Politics of Public Health* (New Brunswick, New Jersey: Rutgers University Press, 1989).
5. Daniel M. Fox, "AIDS and the American health polity: the history and prospects of a crisis of authority," *Milbank Quarterly* 64(1)(1986): 7-33; idem, "Wealth and the care of sick strangers: Rosenberg, Stevens, and the uses of history for health policy," *Journal of Health Politics, Policy and Law* 16(1991): 169-176.
6. Allan M. Brandt, "The syphilis epidemic and its relations to AIDS," *Science* 239(4838)(1988): 375-380; Paul Farmer and Arthur Kleinman, "AIDS as human suffering," *Daedalus*, special issue, "Living with AIDS," 118(2)(1989): 135-160.
7. Paula A. Treichler, "AIDS, gender, and biomedical discourse: current contests for meaning," in Elizabeth Fee and Daniel M. Fox, eds., *AIDS: The Burdens of History* (Berkeley and Los Angeles: University of California Press, 1988), 190-266; Elizabeth Fee and Nancy Krieger, "Thinking and rethinking AIDS: implications for health policy," *International Journal of Health Services* 23(2)(1993): 323-346.
8. Allan M. Brandt, *No Magic Bullet: A Social History of Venereal Disease in the United States Since 1880* (New York: Oxford University Press, 1987).
9. Gerald M. Oppenheimer, "In the eye of the storm: the epidemiological construction of AIDS," in Fee and Fox, eds., *AIDS: The Burdens of History*, 267-301.
10. Simon Watney, *Practices of Freedom: Selected Writings on HIV/AIDS* (Durham, North Carolina, 1994).
11. William H. Masters, Virginia E. Johnson, and Robert C. Kolodny, *Crisis: Heterosexual Behavior in the Age of AIDS* (New York: Grove Press, 1988).
12. P. D. Cleary, M. J. Barry, K. H. Mayer et al., "Compulsory premarital screening for the Human Immunodeficiency Virus: technical and public health considerations," *Journal of the American Medical Association* 258(1987): 1757-1762.
13. See, for example, K. Leishman, "AIDS and insects," *Atlantic Monthly*, September 1987, 56-72.
14. Michael Fumento, *The Myth of Heterosexual AIDS* (New York: Basic Books, 1989).
15. Katherine Park, "Kimberly Bergalis, AIDS and the plague metaphor," in Marjorie Garber, Jann Matlock, and Rebecca L. Walkowitz, eds., *Media Spectacles* (New York: Routledge, 1993), 232-253.
16. Allan M. Brandt, Paul D. Cleary, Lawrence O. Gostin, "Routine hospital testing for HIV: health policy considerations," in Lawrence O. Gostin, ed., *AIDS and the Health Care System* (New Haven, Connecticut: Yale University Press, 1990).
17. Robin Marantz Henig, "AIDS: a new disease's deadly odyssey," *New York Times Magazine*, 6 February 1983, 36, as quoted in Brandt, *No Magic Bullet,* 201.
18. Randy Shilts, *And the Band Played On: Politics, People and the AIDS Epidemic*, (New York: St. Martin's Press, 1987), xxiii, 630.
19. Ricky Ray died of AIDS in 1992. On AIDS in the schools and AIDS-related discrimination, see David L. Kirp, *Learning by Heart: AIDS and School Children in America's Communities* (New Brunswick, New Jersey: Rutgers University Press, 1989); and R. J. Blendon and K. Donelan, "Discrimination against people with AIDS: the public's perspective," *New England Journal of Medicine* 319 (1988): 1022-1026.
20. J. Schmalz, "Whatever happened to AIDS," *New York Times Magazine,* 28 November 1993, 56-60, 80-86.
21. Elizabeth Fee and Daniel M. Fox, eds., *AIDS: The Making of a Chronic Disease* (Berkeley and Los Angeles: University of California Press, 1992).
22. Sandra Panem, *The AIDS Bureaucracy* (Cambridge, Massachusetts: Harvard University Press, 1988).
23. Albert R. Jonsen and Jeff Stryker, eds., *The Social Impact of AIDS in the United States* (Washington, D.C.: National Academy Press, 1993).
24. John H. Gagnon to Committee, personal correspondence on 25 November 1990; see also John H. Gagnon, "Losing ground against AIDS," *New York Times*, 6 January 1994.
25. David E. Rogers and June E. Osborn, "AIDS policy: two divisive issues," *Journal of the American Medical Association* 270(1993): 494-495; D. C. Des Jarlais, N. S. Padian, and W. Winkelstein, "Targeted HIV prevention programs," *New England Journal of Medicine* 331(1994): 1451-1453.

The Impact of AIDS on American Culture

Richard Goldstein

I recently received a monograph from an instructor at a leading medical school who was teaching a course on the literature of AIDS in order to increase the sensitivity of aspiring doctors. In his curriculum he had included the famous issue of the *New England Journal of Medicine* that contained the first formal description of the then mysterious syndrome. The instructor wanted to make a point to his students about how scientific discourse distances itself, and all of us, from suffering, uncertainty, and death. It may be news that medical papers are now to be considered literature, at least for purposes of deconstruction. My point is that by now there is an ample selection of writing about AIDS in virtually every literary form—from poetry to polemics. Reach beyond the written word, to the performing arts, and it is no exaggeration to say that AIDS is one of the most important subjects of dance, theater, painting, photography, video, and performance today. The major American play of 1993 "Angels in America" has a protagonist with AIDS; the major American musical composition, John Corigliano's "First Symphony" is a fierce response to AIDS; the Whitney Museum's "Biennial"—perhaps the nation's most important show of contemporary art—featured a dozen major works about the epidemic.

Now consider the impact AIDS has had on popular culture. It cannot just be measured in the number of rap songs and Hollywood films about the epidemic, since until very recently there were not many. In a commercial sense, AIDS has no legs. It does not sell to couples out for a night at the cineplex. And in terms of pop music iconography, the epidemic cannot compare to bustiers and cop killers. But our entire sense of sexuality has changed in no small part because of AIDS. Our erotic fantasies have had to be renegotiated; some would say that the surge of violence and fetishism in pop culture has much to do with the terror that now surrounds sex. And so does the proliferation of horror films in which bodies are snatched by alien organisms entering the bodies of host humans in strikingly unnatural ways.

The 1990s, in terms of culture at least, is surely the age of AIDS. But what is most striking about this impact is how radical a break it is with the traditional ways art and entertainment in America have dealt with epidemics. Europe has provided a rich canon of works about infectious disease, beginning perhaps with Boccaccio and Chaucer, running through Daniel Defoe, whose *Journal of the Plague Year* is regarded as the first significant work of journalism, and continuing in this century with major literary works like Thomas Mann's *The Magic Mountain* and Albert Camus's *The Plague*. In the nineteenth century, tuberculosis was a leading motif in popular entertainments including beloved operas like "La Traviata" and "La Bohème."

To be sure there are literary works by Americans about tuberculosis, but not many. Though epidemics have had a major impact on American history—forcing the evacuation of cities, altering the course of the westward migration, chastening our victories in wars—there are precious few works of the imagination about these formative encounters with disease. Stories like Edgar Allen Poe's "The Masque of the Red Death," novels like Sinclair Lewis's

Arrowsmith, plays like "Sunrise at Campobello," only prove the point that for artists in America, epidemics were regarded as tests of personal morality not great historic events from which essential insights into the human condition can be drawn.

Americans have always viewed their environment as a peaceable kingdom. In this land of purple mountains' majesty, where the skies are not cloudy all day, infectious disease, and the chaos it unleashes, has been second only to homosexuality as an unfit subject for the arts. The great flu epidemic of the early part of this century caused more fatalities in this country than the Great War that preceded it. Yet, though the war became a prime subject for novelists and poets, the epidemic inspired only silence. A two-page passage in Mary McCarthy's *Memoirs of a Catholic Girlhood* describes the experience of a child climbing aboard a train in the east with her parents to see relatives in the west, and arriving at her destination two days later as an orphan. That was life in an epidemic. But American writers as well as painters, composers, and choreographers shied away from this most compelling theme—that is, until AIDS.

Why is this epidemic different from all the other epidemics? At least to artists in America, there are some obvious answers. For one thing, AIDS seemed to single out homosexuals, at least in its early years, and gay men are deeply invested in the arts. The loss to theater and dance alone has been staggering, and because the epidemic has taken its toll in major American cities, it also hit earliest and hardest in the centers of cultural production. Yet some of the most powerful works about the epidemic have been created by women: Karen Finley, Diamonda Galás, Kiki Smith, and Susan Sontag. These artists, working in various forms, were inspired not just by intense empathy with gay men, but by a profound understanding of stigma and its relation to the body. They, too, were implicated by the metaphor of tainted blood, the fear of punishment for sexual dissidence, the relationship between desire and denial. Sontag's story "The Way We Live Now," which first appeared in the *New Yorker*, was one of the first imaginative works to represent the sudden incursion of an epidemic into middle-class society, what Camus referred to as "death from the clear blue sky."

But empathy is only part of the reason so many artists, particularly women artists, have been drawn to AIDS as a subject. There is also the need to counter stigma and hysteria, which, particularly in the epidemic's early years, threatened people with AIDS and, indeed, every homosexual with what one might call the second death of social isolation, even unto literal quarantine. It is difficult to conjure up today what it was like to be caught up in the terror and rage of America in the early days of AIDS. Something utterly threatening to the peaceable kingdom had entered the culture; something that was not supposed to be there—an incurable disease related to an unmentionable sexuality.

Which institutions in American life were willing to stand up to the belief that sexual permissiveness had put a deadly crack in this nation's armor? The media, the political culture, the religious establishment—all essentially turned away from the crisis. Movies, television, music—those great liberalizing forces in American life—all fell into a silence. It was left to the arts to make noise, to counter denial, and to force Americans to experience the epidemic from the perspective of those at risk. Here was a mission not so different from what artists had undertaken during the Vietnam War: to inspire resistance, and to shatter the distancing devices of official discourse.

What poetry and song lyrics attempted during the sixties became in the age of AIDS the task of theater, video, performance, and the visual arts. A polemic that made use of techniques borrowed from advertising gave us messages like "silence = death." Larry Kramer's drama, "The Normal Heart," sought to shock the gay community into sexual restraint,

even as it railed against the indifference and bigotry of heterosexual society. Yet even at their most didactic, art works about AIDS, from the start, enlisted the full arsenal of aesthetic techniques. Kramer borrowed from the social realism of Ibsen. Diamonda Galás mixed blues refrains and ancient Greek mourning chants in her "Plague Mass," keening and shrieking under blood red lights. John Corigliano borrowed the epic tonalities of Shostakovich to give his "AIDS Symphony" the anguish that great Russian composer had drawn from the siege of Leningrad. He even used a tarantella, a dance that mimics the bite of the tarantula, to signify the onset of dementia in a hectic melody that ultimately collapses into tonal incoherence.

No matter how artists were enjoined by AIDS activists to abandon aesthetics in favor of agitprop, even the earliest works about the epidemic have a formal integrity that denotes a full engagement with the western cultural tradition. No matter how determined these artists were to be direct about their rage, they could only express it in relation to the artistic values of their time. The result is a body of work that is about art as much as it is about AIDS. And because so many of these artists were able to infuse their social and emotional commitments with canon and craft, their work carried an enormous resonance, careening from classicism to post modernism, from earnestness to irony, from drag show to Greek tragedy.

Many have seen the Names Project quilt, either serving as a backdrop to an AIDS conference, or stretched out across the Washington ellipse. By now it is the size of several football fields, and those who walk along its cloth paths can glimpse the epidemic in its full sweep, and yet in intensely individual terms. Artistic assumptions make this project what it is. Here is a work of social protest that draws from the quiltmaking tradition and its associations with the communal, the caring, the feminine. But the "AIDS quilt" also draws from the strategies of conceptual art. It is highly mobile and de facto, as befits a population unlikely to be commemorated by any permanent public monument. It is democratic—anyone can make a panel for a friend—and highly political. Someone made a panel for Roy Cohn. It reads "Bully, Coward, Victim." That epitaph, like the slogan "silence = death," could only have emerged from a process that fuses activism and art.

If the function of art about AIDS were only to counter stigma and teach responsibility, a time should come when these goals are reached. In a crude sense they have been. We seem to have avoided the worst excesses of the punitive imagination, the tattooing and shunning that once seemed imminent. By now the epidemic so pervades the culture that no amount of agitation tells us something we are not already experiencing in our dreams. Furthermore, the mass culture machine, which was once so inhospitable to works about AIDS, is now ready to embrace the subject. "The Normal Heart" is slated to become a Barbra Streisand production. The film, "Philadelphia," the first AIDS drama by a major Hollywood director, garnered several Oscars. At nearly every Madonna concert, the star reminds us of all the friends she has lost. AIDS is now a fit subject for a primetime special, a sort of "new condoms of '93" review, featuring songs and comedy skits along with a relentless safe sex message. The mainstreaming of AIDS may seem ludicrous but is far preferable to the fear mongering and melodramatizing with which the media greeted the epidemic during its early days.

Indeed, the humanization and normalization of AIDS may be the greatest accomplishment of post-war American society, due in no small part to the agitation of artist activists. Now that the indifference has grown more subtle, and the epidemic itself has become more diffuse, one would think artists would turn their attention elsewhere. Instead, the number of works about AIDS is greater than ever. One critic estimates that several thousand painters and photographers are dealing with the subject. By now, there are AIDS oratorios, along with ballets, masses, mixed media works, and even comedies. In a city

like New York, where red ribbons come in rhinestone, art about AIDS is chic.

As the audience for this work grows larger, and critics grow more attentive, artists are becoming more ambitious. Freed from the task of making polemics, they are beginning to explore ideas and emotions once considered anathema to AIDS activism: grief, guilt, and—even trickier for modern audiences—transcendence. Tony Kushner, author of "Angels in America" regards himself as "a new kind of thinker about the epidemic and its larger implications." Though he calls "The Normal Heart" the "great prototype" of an AIDS drama, Kushner hastens to add that that kind of wake-up call is not needed anymore. Instead of Kramer's hectoring broadsides, Kushner's play is lushly imagistic, and though it can be unsparing in its depiction of disease, Kushner is unafraid to temper his naturalism with the symbolic in order to tap into the unconscious. "Angels in America" is typical of what might be called second-generation art about AIDS.

Working in a wide variety of styles and virtually every medium, artists are providing us with what politics cannot, and religion for the most part will not: a ritual of mourning. Why should mourning be such an issue in AIDS? The critic and AIDS activist Douglas Crimp suggests that homophobia, which distorts relationships and disrupts the capacity for intimacy, makes it especially difficult for gay men to grieve. Consider the typical obituary for a gay man who died of AIDS, the way it refers to his lover of many years as a companion, if it refers to him at all; the way it avoids any mention of the sexual identity that was so central to the deceased. Often enough, it also avoids mentioning the disease that killed him. Consider this obituary, and you may understand why Crimp says of AIDS, "Seldom has a society so savaged people during their hour of loss." All the more reason for art about AIDS to deal with what the culture will not, unearthing the full range of signs and symbols that must be confronted if healing is to occur.

Because art about AIDS also involves the assertion of sexuality, it is often bluntly physical. The body is on full display, equipped with what, in medieval times, might have been called tokens of disease. The Kaposi's sarcoma lesion has become part of the make-up artist's armamentarium, though, often enough, the actors' lesions are real. Even in an aggressively ethereal medium like dance, AIDS has shifted the sense of the body and created a new vocabulary to mimic the movements of the dying. In "Absence," choreographer Bill T. Jones wraps his dancers in bed sheets borrowed from his dead partner and lover's hospital ward. The music is Berlioz at his most lyrical, but the movement is halting and pained. It is this contrast between mortality and morbidity, between devotion and loss, that Jones wishes to explore. In order to do that, he must break the cardinal rule of dance, that the body should be beautiful. To prove this point, at one performance, Jones appeared on stage carrying a member of his own company in the late stages of AIDS.

That sense of the body invaded and revealed permeates work about AIDS in every medium. Consider the recent installation of Kiki Smith, in which various bodily fluids are encased in pharmacy jars, each labeled with neat gothic script. "You read everything through AIDS," says Smith. Your perception of aging and vulnerability changes. The meaning of thinness changes. Even the concept of transfiguration takes on a visceral almost clinical edge as in this climactic speech from "Angels in America":

> God splits the skin with a jagged thumbnail, from throat to belly and then plunges a huge filthy hand in. He grabs hold of your bloody tubes, and they slip to evade his grasp. But he squeezes hard, he insists. He pulls and pulls until all your innards are yanked out, and then he stuffs them back, dirty, tangled and torn. It's up to you to do the stitching.

This is a long way indeed from the deathbed wedding in "The Normal Heart." If gay art since Walt Whitman has been about singing the body electric, in the age of AIDS it is about revealing the body repressed, the soul in pain. "See the signs I try to make with my hands and fingers," the artist David Wojnarowicz (whom you may remember as a target of Jesse Helms) wrote shortly before his death from AIDS. "See the vague movements of my lips among the sheets. I'm a blank spot in a hectic civilization, a glass human disappearing in the rain."

To return to my original question: why has this epidemic had such a deep and direct impact on American culture? The answer has partly to do with our faith in art, and partly with the failure of other institutions to deal with the issues raised by AIDS. These issues include not just homosexuality, but all sexuality. The anxieties raised by the sexual revolution, which were always under the surface of liberation rhetoric, came home to roost in the specter of death in youth, which was supposed to have been banished, at least from civilian society. Then there is the failure of science to save us, an enormous collective trauma whose implications go far beyond AIDS. Finally, there is the gap between therapeutic and diagnostic care, creating a huge cohort of people designated HIV positive and forced to bear an unprecedented burden of stigma and uncertainty. These new yet ancient states of being have produced a unique set of anxieties that medicine cannot treat, politics cannot allay, and religion cannot explain. Into this vacuum of signification rushes the artist, giving meaning to the meaningless, form to the chaotic, and witness to the unmentionable. Of necessity in the age of AIDS, the artist is both penitent and priest.

Part III

The International Consequences of AIDS

Pestilence and Restraint: Haitians, Guantánamo, and the Logic of Quarantine

Paul Farmer

> The awkward fact with which U.S. policy wrestles is that people flee the world's Haitis for a combination of motives. All are deserving of some compassion, but how much? *Newsweek*, 1 December 1991
>
> Haitians are the immigrants that Americans love to fear and hate. Robert Lawless, *Haiti's Bad Press* (1992)

Haiti, it is well known, is a country long wracked by political turmoil. But the *coup d'état* of September 1991, was unique in many respects. Most significantly, it represented the overthrow of Haiti's first democratically elected president, and a great deal of military force was required to silence angry opposition to the putsch. More than any of the scores of convulsions preceding it, the coup against Jean-Bertrand Aristide's government generated refugees, many of them young people active in the pro-democracy movement. Once outside of Haiti, these refugees collided with a series of structures and opinions long in the making. For those who fled Haiti by sea, the collision would be, clearly, with United States immigration policy. But these "boat people" would also come up against a host of preexisting notions about Haiti and Haitians—a widely held "folk model" clearly reflected in much American popular commentary on Haiti from the time of its independence in 1804 to the days of the current crisis.[1]

Perhaps nowhere have these preconceptions and prejudices had greater effect than in the lives of a few hundred HIV-positive Haitians detained for up to two years on the United States naval base at Guantánamo Bay, Cuba. "U.S. Base Is an Oasis To Haitians," reads the headline of a 28 November 1991 article in the *New York Times*, often termed our national paper of record. The perspective of Yolande Jean, interned there for eleven months, is somewhat different from that of the *Times:*

> We were in a space cordoned off with barbed wire. Wherever they put you, you were meant to stay right there; there was no place to move. The latrines were brimming over. There was never any cool water to drink, to wet our lips. There was only water in a cistern, boiling in the hot sun. When you drank it, it gave you diarrhea. . . . Rats crawled over us at night . . . . When we saw all these things, we thought, it's not possible, it can't go on like this. We're humans, just like everyone else.[2]

It is useful to step back and examine the origins of this "oasis." Guantánamo, an otherwise full-fledged United States military base, is located roughly a third of the way between Haiti and Florida on the island of Cuba. In 1903, Guantánamo was leased "indefinitely" to the United States for $2,000 per year, and, by the terms of the lease, is not subject to Cuban laws.[3] Had Yolande Jean been on the other side of the fence separating the base from Cuba,

she would not have been expelled, as Cuba does not restrict immigration or entry to those who are HIV negative. Instead, she might have been placed in an AIDS sanitorium. A recent article from the *New England Journal of Medicine* (which might be termed medicine's journal of record), describes one of these sanatoriums:

> Located in a suburb of Havana, Cuba's main quarantine facility is largely fenced in and is composed of barracks housing hundreds of people. Since inspectors from other nations have not been permitted to report on conditions in the quarantine facility, it is impossible to know how much better or worse they are than those at Guantánamo.[4]

In reality, it is not "impossible to know how much better or worse are conditions than those at Guantánamo." First, it has been possible to visit these facilities and to interview HIV-positive persons living there. The Cuban AIDS program has hosted visitors from North America and elsewhere. Many have been highly critical of the sanatoriums, but none of their reports have described situations similar to those depicted by the Haitians on Guantánamo. In 1991, anthropologist Nancy Scheper-Hughes interviewed a number of internees in the Santiago de las Vegas sanitorium. The comments of Patricia, the wife of a soldier who contracted HIV infection while doing military service in Africa, were not atypical of those interviewed by Scheper-Hughes. Like Yolande Jean, Patricia was asymptomatic and found to be HIV positive through mass screening. Like Yolande Jean, Patricia was separated from her children. But the tenor of her comments is strikingly different from those of the Haitian woman:

> Naturally, one feels homesick. You miss your children a great deal. But our needs and the needs of our children are taken care of and we have to accept our situation with as much good will as we can.
>
> We celebrate Mother's Day, we go out on excursions to the movies, to the beach, to watch baseball games. And, of course, those of us who are responsible may go home on the weekends or, if you live far away as we do, on a longer visit. Now I feel like I am a stranger when I am away from the sanitorium and walk down the street in my own community.[5]

The above scenarios—that on Guantánamo and that on the outskirts of Havana—would seem to describe settings that are phenomenologically quite distinct. Each, certainly, is found on the same Caribbean island. In both cases, individuals find themselves restrained against their will by a state that uses force in the name of public health. The architects of these policies cannot look to the historical record for support for these approaches, for quarantine has never been shown to be an effective measure in containing sexually transmitted diseases. In short, both Guantánamo and the Cuban AIDS Program are misguided public health initiatives.

But the similarities evaporate rather quickly upon closer examination of Guantánamo and Santiago de las Vegas. If these two settings are so different, what forces would lead commentators to suggest that they are similar? In what cultural and political contexts are these commentaries embedded? How are the events on Guantánamo linked to the logic of quarantine that underlies such responses to HIV infection? What symbolic work do they perform?

The rest of this essay will attempt to answer these questions by examining the experience

of Yolande Jean and other Haitians detained on Guantánamo. There are conflicting accounts, even by eye-witnesses, as to what happened there. The version offered here—that of the detainees—will be shown to differ significantly from the accounts offered by journalists, United States government officials, and even by the Haitians' lawyers.[6]

Although Cuba is the stage on which were played out the contrapuntal dramas of Yolande and Patricia, Haiti and the United States are the nations most centrally concerned in the intersection of events and processes that led to Yolande Jean's detention. The United States Immigration and Naturalization Service (INS) has long argued that Haitians are "economic refugees," fleeing poverty. For ten years, including the last four of the Duvalier dictatorship and six years of military juntas, the United States, in defiance of international law, forcibly returned Haitian refugees to their country. This process was the result of an arrangement, brokered in 1981, by which the government of Jean-Claude Duvalier permitted United States authorities to board Haitian vessels and to return to Haiti any passengers determined to have violated the laws of Haiti. The United States granted asylum to exactly eight of 24,559 Haitian refugees applying for political asylum during that period.

In the two weeks after the coup of 1991, with the attention of the world press fixed on Haiti, the United States suspended this practice of *refoulement*. As the military continued to arrest and execute partisans of the overthrown President Aristide, refugees streamed out of Haiti, both by sea, to the United States, and by land, to the Dominican Republic. The number displaced in the first three months after the coup has been conservatively estimated at 200,000.

On 18 November 1991, with an estimated 1,500 Haitians already dead and military repression churning full throttle, the administration of George Bush announced that it was resuming forced repatriation; those intercepted would be returned to Haiti without being interviewed by the INS. The United Nations High Commissioner for Refugees announced, the following day, his "regrets that the U.S. Government has decided to proceed unilaterally and return a number of asylum-seekers to Haiti."[7] The process was also denounced by human rights organizations, several of which sued the Bush administration when the first groups of refugees were returned to Haiti. The case eventually ended up before the United States Supreme Court, which ruled in favor of the United States government. Professor Kevin Johnson of the University of California writes of the high court's "shameful acquiescence" to the Bush administration:

> The courts were the last constitutionally viable means by which to halt the Executive Branch's unlawful treatment of the Haitians. As the constitution mandates, the Judiciary must check the excesses of the Executive. The Rehnquist Court, however, consistently deferred to the Executive Branch on immigration matters and refused to assert the Judiciary's constitutional role in reviewing challenges to the interdiction program. The Haitians, in this instance, suffered from that abdication.[8]

There was otherwise little public outcry about the matter, but human rights advocates were able to force a compromise: the refugees would be brought to the naval base at Guantánamo. Shortly thereafter, scores of canvas tents were erected within the confines of the base. "The military and Coast Guard emphasize that theirs is a humanitarian mission," explained the *New York Times*.[9]

In the eight months following the coup, 34,000 Haitians were intercepted on the high seas by the United States Coast Guard; the majority of these refugees were transported to

Guantánamo. Conditions in the camp were grim: the inmates lived in tents and other makeshift shelters on a landing strip, surrounded by barbed wire. These shelters, according to the Haitians, were infested with rats, scorpions, and snakes. The lodgings were permeable to rain, and sanitary facilities were often unavailable. Yet, despite these significant environmental deficiencies, the detainees' chief complaint was of mistreatment by their American hosts.

Shortly after the arrival of the first refugees, rumors of mistreatment, including beatings and arbitrary detention, began to filter through the Haitian advocacy organizations based in the United States. It was difficult to confirm the rumors, as the U.S. military restricted access to the base. Even as uncritical stories based upon military briefings appeared in the mainstream press, a group of journalists sued the United States government for access to the base. Ingrid Arnesen of *The Nation* reported one of the first stories upon visiting Guantánamo. One of the detainees, who had been on the base for over a year, spoke to Arnesen in no uncertain terms:

> Since we left Haiti last December we've been treated like animals. When we protested about the camp back then, the military beat us up. I was beaten, handcuffed and they spat in my face. I was chained, made to sleep on the ground. July, that was the worst time. We were treated like animals, like dogs, not like humans.[10]

In short, the Haitians and their advocates soon failed to see the human aspect of this "humanitarian mission." By the middle of 1992, there were the usual divergent readings of what was happening on the base. Stories in the mainstream United States media continued to portray Guantánamo as a haven for refugees. Haitians, including the Haitian print and radio media, tended to refer to the base as a "concentration camp," a "prison," or, at best, "a detention facility."

Curiously enough, the Bush administration's reading seemed to be more in line with that popular among Haitians. They realized that refugees were being detained on the base for long periods of time—some almost two years—without a meaningful hearing. In response, the administration gathered some of the nation's leading legal talent—to justify this practice. Since Guantánamo is not technically on United States soil, the Bush administration lawyers developed the following rationale:

> While conceding that the Haitians are treated differently from other national groups who seek asylum in the U.S., the Government claimed that the U.S. Constitution and other sources of U.S. and international law do not apply to Guantánamo—this despite the fact that the U.S. military base at Guantánamo is under the exclusive jurisdiction and control of the U.S. Government.[11]

Most Haitians listen to radio; anyone who did so in the early months of 1992 came to know Guantánamo as a place best avoided. Meanwhile, military repression of the Haitian popular movement continued apace: anyone associated with community organizing or the democratic movement was branded as subversive. Yolande Jean's case is instructive. Both Yolande and her husband Athénor were members of Komite *Inite* Demokratik, a democratic organization founded shortly after Duvalier's departure; Yolande was heavily involved in adult literacy projects. After the coup, both Yolande and Athénor were subjected to many

threats. On 27 April 1992, Yolande was arrested and taken to Recherches Criminelles, the police station that serves as the headquarters of Colonel Michel François, with whom Haiti's death squads are intimately associated. The interview was something more than perfunctory; during the course of her torture, Yolande, visibly pregnant with her third child, began to bleed. On her second day in prison, she miscarried.

Yolande decided at that moment that, were she to survive detention, she would flee the country. Perhaps because there was, at the time, a movement among the Haitian business elite to resume negotiations to end the embargo, Yolande was released from prison the following day. Shortly thereafter, she stowed her sons with a kinswoman and headed for northern Haiti. Her husband remained in hiding. She would not see him again.[12]

> I took the boat on May 12, and on the 14th, they came to get us. They did not say where they were taking us. We were still in Haitian waters at the time. . . . We hadn't even reached the Windward Passage, when American soldiers came for us. But we thought they might be coming to help us—there were sick children on board. On the 14th, we reached the base at Guantánamo.[13]

Yolande's initial instinct—that the United States soldiers "might be coming to help us"—was soon subject to revision: "They burned all of our clothes, everything we had, the boat, our luggage, all the documents we were carrying." United States television had displayed images of Haitian boats burning, but the process was described by both the Coast Guard and the media as the destruction of unseaworthy vessels. There was no mention of personal items.

When asked what reasons the U.S. soldiers gave for burning the refugees' effects, Yolande replied:

> They gave us none. They just started towing our belongings, and the next thing we know, the boat was in flames. Photos, documents. If you didn't have pockets in which to put things, you lost them. The reason that I came through with some of my documents is because I had a backpack and was wearing pants with pockets. They went through my bag, and took some of my documents. Even my important papers they took. American soldiers did this. Fortunately, I had hidden some papers in my pockets.[14]

Haiti was full to overflowing with others just like Yolande Jean. Soon, Guantánamo was full to overflowing as well. On 24 May 1992, President Bush issued Executive Order number 12,807 from his summer home in Kennebunkport: referring to the Haitian boats, he said that the Coast Guard was "to return the vessel and its passengers to the country from which it came . . . provided, however, that the Attorney General, in his unreviewable discretion, may decide that a person who is a refugee will not be returned without his consent."[15]

As attorney Andrew Schoenholtz of the Lawyers' Committee for Human Rights wryly observed, "Grace did not abound; all Haitians have been returned under the new order."[16]

The bottom line: all Haitians leaving Haiti by sea would be intercepted and returned to Haiti without processing by the INS. This was broadcast, in Creole, by the Voice of America affiliates in Haiti. By the summer of 1992, Haitians under the gun understood that they would find no safe haven outside of the country. Haiti resembled more and more a burning building from which there was no exit. The Bush administration's actions—denying the refugees legal counsel or a hearing, preventing press coverage of the conditions of the

detainees—served to reinforce widely-held beliefs that Haitians had been singled out for racist and exclusionary treatment.

In spite of the odds against all Haitians seeking asylum, Yolande Jean's case for refugee status would seem to have been airtight. She was a longstanding member of an organization targeted for political repression; she and her husband had been arrested and tortured; and she had managed to preserve key documents proving this. In fact, Yolande Jean *was* one of those few refugees who passed scrutiny. As a bona fide political refugee, United States law provided her safe haven. There was one problem: Yolande, like all the refugees, had been tested for HIV, the virus that causes AIDS.

It was inevitable, really, that AIDS, or fear of it, would surface in the course of the Haitian refugee crisis. In the 1990s, HIV is certain to be present in any group of over 30,000 young adults from almost anywhere in the Caribbean. United States legislators at state and federal levels have introduced enormous numbers of bills regarding HIV, most of which have been punitive or restrictive. Although immigration law is in principle strictly separated from laws regarding political refugees, anyone familiar with INS policies toward Haitians could have predicted mandatory screening for HIV. By the time mass screening of all refugees was completed, the United States government had identified 268 HIV-positive refugees.

Although Yolande and many others had already passed the stringent requirements for refugee status and were thus guaranteed asylum, U.S. immigration law was invoked to keep these Haitians out. In contrast, Cubans who hijack planes to Miami or who appear on United States soil through other means are not even tested for HIV. Haitians were quick to point this out.

Immigration legislation regarding HIV has a short and undistinguished history. Although legislation to exclude or otherwise punish those with AIDS was introduced shortly after the syndrome was recognized, it was not until 1986 that the Department of Health and Human Services (HHS) was asked to draft laws requiring that aliens seeking to immigrate be tested for and found free of HIV. This legislation was sponsored in the Senate by Senator Jesse Helms and was approved—unanimously—in June 1987. "This Senate action was extraordinary," notes a legal opinion, "in that it assumed a responsibility, previously entrusted exclusively to the HHS, to determine which communicable diseases would be grounds for excluding aliens."[17]

Public health specialists spoke out against this policy, which they regarded as unwarranted. Debate around this issue led, in fact, to a reconsideration of several other disorders on the list. The U.S. Centers for Disease Control came to argue, by 1990, that HIV and all other sexually transmitted pathogens should not be grounds for exclusion. They recommended that only active pulmonary tuberculosis remain on the list, and a second bill, reflecting their expert opinion, was introduced to Congress. Notes lawyer Elizabeth McCormick:

> opposition to the [second] bill was led by Sen. Jesse Helms, who considered the proposal an attempt to appease the AIDS lobby and the "homosexual rights movement which fuels it." Sen. Helms claimed that HHS was not acting in the interest of the public health but was "promoting an agenda skewed to placate the appetite of a radical and repugnant political movement."[18]

These debates played themselves out on Guantánamo. Again, the experience of Yolande Jean is instructive, for it reveals the repercussions of both arbitrary laws and arbitrary proceedings:

> They sent me to Camp Number 3, to have a blood test. They didn't specify what test they were doing, but everyone had one. The others [who had been classed as bona fide political refugees] were authorized to leave for the United States. There I was, and they didn't call me . . . I was the last person left in the Camp. After three days of waiting, they called me. They told me, "You have a little problem." They asked my age, they asked for a photo ID. They told me I had a little problem, but they'd send me to see a doctor . . . and help resolve everything for me. After 22 days, they said, "You'll be fine, you'll go to the United States." I asked what sort of problem they were referring to. They said, "It's a little virus you have." I replied, "There's no such thing as a little virus, speak clearly so that I can understand." They put me in a small room, and eight soldiers surrounded me. . . . I told them not to touch me. "Don't worry," they said, "you'll be cured." I told them to speak clearly so that I could understand. Even the interpreter couldn't explain. Tell me! I see what you're saying—that I have AIDS. Fine, I have AIDS. Don't tell me, then, that you'll cure me. That in 22 days I'll be fine! At that point, two military police turned me around, grabbed me by both arms in order to put me on the bus for [Camp] Bulkeley.[19]

Out of encounters such as this was born the "HIV detention camp" on Guantánamo, Camp Bulkeley. Inmates were given new bracelets identifying them as HIV positive. As Yolande Jean noted, "They were even harsher with us than with the others," and a group of American lawyers concurred: "[starting] in February 1992 those testing positive were interviewed and required to meet a higher standard to establish that they had a 'wellfounded fear' of persecution. The Immigration and Naturalization Service denied requests by the refugees' attorneys to be present at these interviews."[20]

In the spring of 1993, Judge Sterling Johnson, a Bush appointee who years earlier had himself been an officer on Guantánamo, heard the case brought against the United States government by the Haitians and their advocates. The more depositions he heard, the more convinced he became that the detentions of the HIV-positive Haitians represented "cruel and unusual punishment" in violation of the Eighth Amendment of the U.S. Constitution. In his 1993 ruling on the case, he described Camp Bulkeley as follows:

> They live in camps surrounded by razor barbed wire. They tie plastic garbage bags to the sides of the building to keep the rain out. They sleep on cots and hang sheets to create some semblance of privacy. They are guarded by the military and are not permitted to leave the camp, except under military escort. The Haitian detainees have been subjected to predawn military sweeps as they sleep by as many as 400 soldiers dressed in full riot gear. They are confined like prisoners and are subject to detention in the brig without hearing for camp rule infractions.[21]

As terrible as this sounds, the stories told by the Haitians interned there are even worse. While the U.S. press wrote of the detainees as unfortunates caught in a bureaucratic limbo, the Haitians spoke of more active processes. Yolande Jean recalled the events of 17 July 1992:

> We had been asking them to remove the barbed wire; the children were playing near it, they were falling and injuring themselves. The food they were serving us, including canned chicken, had maggots in it. And yet they insisted that we eat it. Because you've got no choice. And it was for these reasons that we started holding demonstrations.
>
> In response, they began to beat us. On July 18th, they surrounded us, arrested some of us, and put us in prison, in Camp Number 7. . . . Camp 7 was a little space on a hill. They put up a tent, but when it rained, you got wet. The sun came up, we were baking in it. We slept on the rocks; there were no beds. And each little space was separated by barbed wire. We couldn't even turn around without being injured by the barbed wire.[22]

For the Haitian refugees, then, Guantánamo represented a health hazard rather than an oasis. Even without subjecting the detainees to privations such as those described, it was unsafe to keep over 200 HIV-positive persons cramped together in such close quarters. This brings to the fore the question of medical care for the HIV-positive refugees and their dependents: who was providing it, and how?

The camp was served by a Battalion Aid Station clinic staffed by two military physicians, one specializing in infectious disease and another in family practice. Again, commentary on this version of the doctor-patient relationship tends to appear as positioned rhetoric. To quote the *New England Journal of Medicine*:

> That the military physicians worked hard to treat the Haitians at the camp was not in dispute. Nonetheless, Judge Johnson concluded that "the doctor-patient relationship has been frustrated." The Haitians believed that the military physicians were involved in their continued detention, and there were also great cultural differences between the physicians and the Haitian patients. As a result, the patients did not trust either their diagnosis or the medications prescribed for them.[23]

In all that regards Haiti, attributing diverging interpretations of a situation to "great cultural differences" has been a recurrent theme. But Yolande Jean did not refer, even once, to cultural differences as an explanation of the substandard medical care. She spoke, rather, of the abuse of power:

> They gave me two pills and an injection. I asked them, why the injection? Because you have a little cold, they replied. But it wasn't a vaccine, it was an injection in the buttocks. And if you didn't want it, you had no choice: they simply said, it's for your own good, you have to accept it, or they call soldiers to come and hold you, force you to take it or they put you in the brig and bring your pills to you there. There were people who refused to have their blood drawn; soldiers came to handcuff them, tie them up in order to draw their blood.
>
> I learned that the injection the doctor had given me was Depo-Provera. I began having heavy bleeding, I bled for three months, lost weight. There were other women who'd had the injection before me, but I didn't know that. If I'd learned of this ahead of time, I would've tried to warn the others and prevent their receiving it. . . . When I learned this, I tried to stop them. No, I said, you will not commit this crime.[24]

The degree to which cultural difference is invoked serves as a marker, it seems, for the degree to which commentators are uncomfortable with full exposure of what happened on Guantánamo. It never figured in the commentaries of the Haitians, even though the concept of cultural distinctness is widely deployed in Haiti. The refugees interviewed spoke of forced blood draws and forced medication; they spoke of the brig, of solitary confinement, of barbed wire. And yet, even the Haitians'advocates—their lawyers—failed to capture the refugees' outrage over this treatment. To quote one of the lawyers:

> The military doctors are probably moved by humanitarian and population control objectives. On the one hand, the doctors may be concerned that HIV+ refugee women who get pregnant pose a serious health risk to themselves and their babies. on the other hand, the doctors are also undoubtedly eager to limit the growth rate of the refugee population on Guantánamo, particularly because it is a population which has a high prevalence of HIV infection.[25]

In June 1992, the prisoners, organized by, among others, Yolande Jean, began holding peaceful demonstrations. These were met, according to those interviewed, with intimidation, open threats, and detention in the brig. In July, the prisoners rioted, and responded to the soldiers, dogs, and aluminum batons with rocks. About 20 inmates were arrested and placed in Camp 7, in near-solitary confinement.

Outcry over Guantánamo came late, but it eventually became an issue in the 1992 United States presidential election. Prior to the adoption of the cynical *Realpolitik* of President Clinton, the official platform of the Clinton-Gore ticket qualified George Bush's treatment of the Haitian refugees as "inhuman." One of the planks, called simply, "Stop the Forced Repatriation of Haitian Refugees," read as follows:

- Reverse Bush Administration policy, and oppose repatriation.
- Give fleeing Haitians refuge and consideration for political asylum until democracy is restored to Haiti.
- Provide them with safe haven, and encourage other nations to do the same.[26]

The platform also quite specifically promised to "Stop the cynical politicization of federal immigration policies. Direct the Justice Department to follow the Department of Health and Human Services' recommendation that HIV be removed from the immigration restrictions list."[27]

As the presidential campaign heated up, it became clear that Clinton's proposed policy toward Haitian refugees would not be his most popular one. The cover of the September 1992 edition of *USA Today* carried a photograph of a huddled mass of Haitian refugees, some of them children, on the decks of a Coast Guard cutter. "As compassionate as Americans try to be," asked the caption, "can we realistically afford an open border policy?"[28] One read, in some newspapers, of "the outrage over treatment of the Haitian refugees," but this outrage was strangely absent from other manifestations of public opinion, which may have been more accurately reflected in the comments of immigration officials. One Associated Press reporter interviewed Duke Austin, special assistant to the director of congressional and public affairs at the INS. Mr. Austin could not understand all the fuss about the HIV-positive internees: "They're gonna die anyway, right?"[29]

In the same edition announcing "Boat with 396 Haitians Missing; Cuba reports 8 sur-

vivors," the *Orlando Sentinel* wrote of "what could be a huge problem for the state: an explosion of Haitian migrants to South Florida." The story, which ran on the front page, continued by noting that "Many fear that tens of thousands of refugees could sail for Miami around Inauguration Day, 20 January, because of President-elect Bill Clinton's pledge to give Haitians a fair hearing for political asylum in the United States."[30] On 28 January, however, Clinton began backpedaling, stating that he would be continuing his predecessor's policies. Hearing of this, a number of refugees detained on Guantánamo began a hunger strike. Yolande Jean was the leader of this movement:

> Before the strike, I'd been in prison, a tiny little cell, but crammed in with many others, men, women, and children. There was no privacy. Snakes would come in; we were lying on the ground and lizards were climbing over us. One of us was bitten by a scorpion . . . there were spiders. Bees were stinging the children, and there were flies everywhere: whenever you tried to eat something, flies would fly into your mouth. Because of all this, I just got to the point, sometime in January, I said to myself, come what may, I might well die, but we can't continue in this fashion. We called together the committee, and decided to have a hunger strike. Children, pregnant women, everyone was lying outside, rain or shine, day and night. After 15 days without food, people began to faint. The colonel called us together and warned us, and me particularly, to call off the strike. We said no. At four in the morning, as we were lying on the ground, the colonel came with many soldiers.
>
> They began to beat us—I still bear a scar from this—and to strike us with nightsticks. . . . True, we threw rocks back at them, but they outnumbered us and they were armed.
>
> They then used big tractors to back us against the shelter, and they barred our escape with barbed wire.[31]

Yolande Jean was arrested and placed in solitary confinement. This version did not make it into the *New York Times*, which reported only that "at least seven Haitian refugees protesting their detention here by refusing food have lost consciousness."[32] No mention was made of any retribution on the part of the strikers' wardens.

Even the Haitians' lawyers, who reached the base in the middle of the strike, seemed a bit annoyed by their actions. "The hunger strike took us all by surprise, especially given the fact that the litigation team is in the middle of settlement negotiations with the Department of Justice."[33] The Haitians, it seems, were no longer impressed by bureaucratic efforts to have them released. They continued what some of them termed "active, nonviolent resistance." On March 11, eleven prisoners attempted to escape to Cuba, but were recaptured. Two of the detainees tried to commit suicide, one by hanging. A letter from Yolande Jean to her family was widely circulated in the community of concern taking shape in response to the situation on Guantánamo:

> To my family:
>
> Don't count on me anymore, because I have lost in the struggle for life. Thus, there is nothing left of me. Take care of my children, so they have strength to continue my struggle, because it is our duty.
>
> As for me, my obligation ends here. Hill and Jeff, you have to con-

> tinue with the struggle so that you may become men of the future. I have lost hope; I am alone in my distress. I know you will understand my situation, but do not worry about me because I have made my own decision. I am alone in life and will remain so. Life is no longer worth living to me.
>
> Hill and Jeff, you no longer have a mother. Realize that you don't have a bad mother, it is simply that circumstances have taken me to where I am at this moment. I am sending you two pictures so you could look at me for a last time. Goodbye my children. Goodbye my family. We will meet again in another world.[34]

The Haitians' advocates, including Haitian refugee groups in the eastern United States, stepped up their pressure. On 26 March 1993, Judge Johnson of New York again ruled against the administration. He ordered that all detainees with fewer than 200 T-lymphocytes per cubic millimeter be transferred to the United States. It was the first time that T-cell subsets were mentioned in a judicial order.

Finally released from internment by the direct order of a federal judge, the refugees came in small groups, Yolande almost directly from solitary confinement. They arrived on the American mainland before dawn on 8 April 1993. At the beginning of the summer, over 150 Haitians still remained on the base, and a second hunger strike was initiated. Eventually, these actions, in concert with the legal and moral pressures brought to bear on the United States government, led to the closing of what Judge Johnson would call "the only known refugee camp in the world composed entirely of HIV-positive refugees." Like its predecessor, the Clinton administration had failed to prove that Haitians like Yolande Jean warranted "the kind of indefinite detention usually reserved for spies and murderers."[35]

The detention of HIV-positive Haitian refugees raises a host of questions regarding a complex symbolic web linking xenophobia, racism, and a surprisingly coherent "folk model" of Haitians held by many North Americans. The persistent notion of Haitians as infected and, more importantly, *infecting*, has clearly underpinned much of the American response.[36] One lawyer has acutely observed that "The exclusion of HIV-infected Haitian refugees flows from the once firmly held perceptions that Haiti is the birthplace and primary source of the HIV virus and that most Haitian refugees are fleeing economic hardship rather than political persecution."[37]

In analyzing these issues, it is useful to examine the use of the United States legal system to buttress an illegal policy towards Haitians. The policies elaborated by the Bush administration ostensibly rely more on the rule of law than on any moral principles, but they violate a number of preexisting laws. Among the many United States and international laws violated by the forced repatriation of self-proclaimed refugees are the Immigration and Nationality Act and the United Nations Convention Relating to the Status of Refugees. A human rights lawyer summarizes the legal case to be made against his own government's policy:

> The U.S. policy of forced repatriation violated international legal obligations of the United States under Article 33 of the Protocol relating to the status of Refugees and undermines the credibility of the U.S. commitment to international law in the eyes of the rest of the world. The United States correctly condemned the forced repatriation of Vietnamese asylum-seekers from Hong Kong following flawed screening procedures and also criticized the Malaysian and Thai governments for pushing back boats filled with

> Vietnamese asylum-seekers. The horrific human rights violations since the September 1991 coup render especially cruel the U.S. practice of forcibly repatriating all Haitians without even attempting to determine who among them might fear persecution at the very hands of the Haitian armed forces waiting for them at the dock in Port-au-Prince.[38]

Another lawyer puts it succinctly: "By treating Haitians differently than any other refugee group, the U.S. government has created a two-track asylum process—one for Haitians and one for everyone else."[39]

With legal opinions such as these, how, precisely, did two consecutive United States administrations manage to detain people like Yolande Jean? Certainly, United States lawmakers seem to support the exclusion of HIV-positive entrants: a February 1993 vote on a proposal to remove HIV infection from the list of diseases for which an immigrant may be excluded failed in the Senate by a vote of 76 to 23. Not surprisingly, opposition to the bill was again led by Senator Jesse Helms.

But there is also disturbingly strong popular support for these policies. When public health officials, led by Health and Human Services Secretary Louis Sullivan, recommended that HIV be removed from the list of diseases for which entrants could be excluded, there was a brisk response: "During a thirty-day public comment period following the issuance of Dr. Sullivan's proposal, the HHS received 40,000 letters in opposition to the elimination of HIV infection as a ground for exclusion of aliens."[40]

With or without HIV, Haitians are not welcome, it would seem. As mentioned earlier, South Florida newspapers were full of alarmist headlines, such as that from the 11 January 1991, *Orlando Sentinel*: "South Florida braces for Haitian time bomb." More recently, the 9 August 1993 edition of *Newsweek* consecrated its cover story to the "Immigration Backlash." "A Newsweek Poll: 60 percent of Americans Say Immigration is 'Bad for the Country.'" Haitians fared especially poorly in the sympathy sweepstakes. *Newsweek* pollsters asked, "Should it be easier or more difficult for people from the following places to immigrate to the U.S.?," and offered respondents a list of regions or continents. Only Haiti and China were singled out by name; Haiti fared poorly. Contrary to the rumor of a "groundswell of revulsion" over ill-begotten policy towards Haitians, 20 percent of those polled said immigration should be easier, while 55 percent said it should be more difficult.

After a decade during which less than half of one percent of applicants were granted asylum, one wonders how much more difficult it could be.

The data certainly call into question such constructions as the "public outrage" narrative mentioned above. The trickle of public outrage against the United States-sponsored violation of Haitian detainees' rights paled in comparison to the 40,000 postage stamps worth of outrage against liberal lawmakers who wished to allow HIV-positive refugees into this country.

Discordant stories of Guantánamo pose questions of representation and interpretion of the events and processes that have marked the lives of Yolande Jean and many other Haitians. That there will be dominant and oppositional accounts of what happened on Guantánamo is self-evident; that the accounts of the powerful will be undergirt by solid institutional supports, by those who control the chief modes of symbolic production, is equally unsurprising. But there are interesting and unexpected twists. On Guantánamo, the so-called "oppositional" voices, when coming from the advocates of the Haitians rather than the Haitians themselves, are often similar to the dominant voices more intimately linked to state power. Much of the oppositional criticism of Guantánamo leaves the reader with the impression that the United States military, including their doctors, were themselves

frustrated victims of bureaucratic snarls. The image offered is of unfortunates languishing on a base, and not that of active, malignant harassment.

For example, medicolegal specialist George Annas offers the following assessment in the *New England Journal of Medicine*: "That the military physicians worked hard to treat the Haitians at the camp was not in dispute."[41] But in fact this was in dispute, as Yolande's account reveals. The detainees themselves have an altogether different version of what transpired on Guantánamo, a version that is all too often lost in journalistic and scholarly accounts.

In light of the strong forces constraining candid discussion of Guantánamo, the conclusion of one of the Haitians' lawyers is less surprising: "We need to convince the Clinton people that what we want is reasonable and cost-effective."[42] No need, apparently, to convince the Clinton people that the events on Guantánamo were an abomination and a crime. Journalists know this; lawyers know this.

In their earnest efforts to convince the empowered that their solution was "reasonable and cost-effective," the Haitians' advocates are misrepresenting Guantánamo. They are making the naval base resemble a sanatorium—a misguided public health intervention—when in fact it represents a much more malignant expression of longstanding United States policies toward Haitians.

Notes

1. For an overview of these folk models, see Robert Lawless, *Haiti's Bad Press* (Rochester, Vermont: Schenkman, 1992).
2. The words of Yolande Jean and of other Haitians quoted in this paper derive from interviews conducted by the author. Ms. Jean's name has not been changed, at her own request.
3. In 1912, the annual rent was raised to $5,000. For the text of the Platt Amendment, which formalized these arrangements, see Eric Williams, *From Columbus to Castro: The History of the Caribbean, 1492-1969* (London: André Deutsch, 1970), 420-421.
4. George Annas, "Detention of HIV-positive Haitians at Guantánamo," *New England Journal of Medicine* 329(1993): 592.
5. Nancy Scheper-Hughes, "AIDS and human rights in Cuba—a second look," in "Festchrift in Honor of Charles Leslie," edited by Francis Zimmermann, p. 29. The page numbers to which I refer are those of the manuscript, which is in press (University of California Press). A similar view is offered by Julie Feinsilver, *Healing the Masses: Cuban Health Politics at Home and Abroad* (Berkeley, California: University of California Press, 1993).
6. See n. 2.
7. William O'Neill, "The roots of human rights violations in Haiti," *Georgetown Immigration Law Journal* 7(1993): 115. For a detailed analysis of the *coup d'état of 1991*, see Paul Farmer, *The Uses of Haiti* (Monroe, Maine: Common Courage, 1994).
8. Kevin Johnson, "Judicial acquiescence to the Executive Branch's pursuit of foreign policy and domestic agendas in immigration matters: the case of the Haitian asylum seekers," *Georgetown Immigration Law Journal* 7(1993): 37.
9. 28 November 1991, A6.
10. Cited in *The Nation*, 4/11 January 1993, 5.
11. Cathy Powell, "'Life' at Guantánamo: the wrongful detention of Haitian refugees," *Reconstruction* 2(2)(1993): 59.
12. In October 1993, Athénor Jean was killed by the paramilitary forces then ruling Haiti.
13. See n. 2.
14. Ibid.
15. Cited in Andrew Schoenholtz, "Aiding and abetting persecutors: the seizure and return of Haitian refugees in violation of the U.N. Refugee Convention and Protocol," *Georgetown Immigration Law Journal* 7(1993): 71.

16. Ibid.
17. Elizabeth McCormick, "HIV-infected Haitian refugees: an argument against exclusion," *Georgetown Immigration Law Journal* 7(1993): 157.
18. Ibid., 159.
19. See n. 2.
20. Annas, "Detention of HIV-positive Haitians," 590.
21. Cited in ibid.
22. See n. 2.
23. Annas, "Detention of HIV-positive Haitians," 590.
24. Depo-Provera, a long-acting contraceptive, is an analogue of the hormone progesterone. The forced injection has been discussed—theoretically—by several medical ethicists and adamantly rejected on moral grounds. In legal terms, the forced injection of any substance represents the felony crime of assault.
25. Powell, "'Life' at Guantánamo," 64. As noted above, forced treatment fulfills the legal criteria for the crime of assault.
26. Bill Clinton and Albert Gore, *Putting People First* (New York: Times Books, 1992), 119-120.
27. Ibid., 119.
28. *USA Today*, vol. 121, no. 2568.
29. Cited in *The Nation*, 4/11 January 1993, 5.
30. See "South Florida braces for Haitian time bomb," *Orlando Sentinel*, 11 January 1993.
31. See n. 2.
32. See the article filed by Philip Hilts, *New York Times*, 15 February 1993.
33. Powell, "'Life' at Guantánamo," 60.
34. See n. 2.
35. Cited in Powell, "'Life' at Guantánamo," 68.
36. Paul Farmer, *AIDS and Accusation: Haiti and the Geography of Blame* (Berkeley, California: University of California Press, 1992).
37. McCormick, "HIV-infected Haitian refugees," 151.
38. O'Neill, "Roots of human rights violations," 117.
39. Powell, "'Life' at Guantánamo," 58.
40. McCormick, "HIV-infected Haitian refugees," 160.
41. Annas, "Detention of HIV-positive Haitians," 590.
42. Powell, "'Life' at Guantánamo," 65.

"Unambiguous Voluntarism?" AIDS and the Voluntary Sector in the United Kingdom, 1981-1992

Virginia Berridge

Since the mid-1970s, there has been an upsurge of public and political interest in the role of voluntary organizations both in North America and in Western Europe. The role of the voluntary sector as an alternative to state provision of services has moved center stage. In Britain, the revival of voluntarism was initially associated with the Thatcher government of the 1980s, with its rhetoric of family values and the virtues of self-help.[1] But the roots of the revival of voluntarism lay in what may be broadly termed both Left and Right political perspectives. From the Right, the attack on the welfare state and central state control certainly extolled the virtues of the voluntary sector. From the Left also, there was a desire to recover a lost sense of community, to rediscover the virtues of voluntarism, self-help, and participation, by contrast with the remoteness of state bureaucracies.

The relationship between voluntarism and the state has varied over time, inclining quite significantly to the latter in the United Kingdom in the post-World War II period.[2] But recent legislative changes have brought major redefinitions of the boundaries. In particular, the institution of a quasi-market relationship between "purchasers" and "providers" of health and social care has indicated a greater formal service provision role for the voluntary sector. The National Health Service and Community Care Act of 1990 has developed the concept of a "mixed economy of care" with voluntary organizations playing a central role.[3]

This paper aims to assess the history of one recent development in the United Kingdom voluntary sector, voluntarism and AIDS, in terms of the overall policy context of United Kingdom voluntarism in the 1980s and early 1990s. It focuses on the years just prior to the introduction of community care, although many of the key issues of that later development are inherent in the earlier events. Studies of the policy and social response to AIDS have stressed the importance of the "participatory traditions" of civil society.[4] Mildred Blaxter, in her survey of worldwide AIDS policies, noted that the policies of many European countries had been influenced by the dominant position of the state in health and social welfare. Voluntary organizations had had a role to play in Switzerland and the Netherlands, but little influence in France or Italy, or, until recently, in Eastern Europe.[5]

Blaxter saw Britain as one European country where voluntary organizations had had a role in policy. Yet few studies have so far been made of AIDS volunteering in that country and none from a contemporary history perspective.[6] The role of AIDS voluntary organizations in the United States has been more closely studied than AIDS voluntarism in Britain; the pioneering role of the Gay Men's Health Crisis in New York exemplifies some of the tensions within volunteering in the United States.[7] Yet voluntary organizations played a key role at various stages in AIDS policy formation in Britain and the relationship with the state has been a continuing theme. The advent of the syndrome led initially to an upsurge of self-help, pure and unambiguous voluntarism; as time has passed the relationship of voluntary

and statutory has become closer and more complex. This paper will therefore trace the chronology of the voluntarist response to AIDS in Britain; and will also raise some issues inherent in that history, issues which are relevant not just to the study of the history of AIDS, but also to the recent history of the British voluntary sector in general.

A Three-Stage Chronology?

A three-stage chronology for the history of AIDS and policy formation in the United Kingdom can be identified.[8] The first stage, from 1981 to 1986, was termed one of "policy from below," when policy was beginning to be formed at a departmental level, but was also predicated on the emergence of a "policy community" around the disease, a community composed of emergent medical and scientific experts and also of members of the gay community. This initial stage gave place in 1986-1987 to one of national political emergency. AIDS, from being a departmental policy issue with its attendant policy community, moved center stage. It became a clear political priority, with a consensual cross-party reaction based on national unity against the threat posed by AIDS to the general population. Responses were at a war-time level—a national media campaign, a directed Medical Research Council Programme to develop an AIDS vaccine, vastly increased funding for services and health education. That war-time reaction was relatively shortlived, and was succeeded by a third phase, from 1988 onward, which can be broadly characterized as one of "normalization" and "professionalization." The definition of AIDS itself changed from epidemic to chronic disease. The advent of palliative treatments (primarily AZT) made the condition less immediately lethal and brought the issue of early treatment to the fore. At the policy level, key committees were reconstituted and some of the early pioneers marginalized; at a service level, paid professionals began to replace some of the early volunteers. Policy development, so John Street argued, continued at a rapid pace.[9] But it no longer engendered the same sense of public panic or political urgency. The liberal consensus of "safe sex" and "harm minimization" held its ground, even if there were moves to undermine it. More recently, it can be argued, a new and fourth phase of British policy has begun, marked by repoliticization and significant changes in the liberal consensus, in particular, in relation to testing and screening.[10]

The Early Stage of AIDS Voluntarism: "Unambiguous Voluntarism," 1982-1986

How did the role of voluntarism develop over this period? There was a trajectory from early voluntarist self-help, by way of demands for national coordination, to a phase of "bureaucratic voluntarism." That first phase, from 1981 to 1986, was indeed one, not only of policy from below but of "unambiguous voluntarism."[11] AIDS presented in a policy and a scientific vacuum; and early reactions to the threat it seemed to pose had a voluntarist and self-helping ethos. Despite the gloomy and threatening nature of the cause, there was also a sense in the gay community of intense enthusiasm and commitment as the following recollection (taken at random) illustrates. The volunteer quoted, not seropositive himself, was involved in the early meetings of the group Body Positive:

> Everyone was in constant communication, it was mad, it was hectic . . . fund raising, visiting, a little bit of social life. . . . Everything was HIV and

> AIDS, your whole life was taken over. All that incredible energy, just like gay lib and we were all contributing and feeding off it.[12]

The institutional history of that early voluntary response in terms of London-based organizations has been discussed in more detail elsewhere.[13] A gay self-help group established in the 1970s, the Gay and Lesbian Switchboard, was of central importance in the initial response, organizing the first public conference in the United Kingdom on AIDS in May 1983, and opening up a special helpline after a BBC Horizon program, "Killer in the Village" was broadcast in April 1983. The Horizon program and the May conference also led to the refounding of the Terrence Higgins Trust, which was to become the leading AIDS voluntary sector organization. The Trust had originally been established by friends of Terrence Higgins, who had died of AIDS in 1982. In its earliest incarnation it had a working-class image and was associated with gay biking and leather groups; it focused its attention via benefits in gay pubs, on fundraising for research. In 1983, it was relaunched and many of the Switchboard volunteers, including Tony Whitehead, later Chairman of the Trust Steering Committee, moved over to it. Its new image was middle class, with a focus on health education, educating the gay community about the danger it faced, but also having a concern to influence government policy. Other London-based organizations were established. Body Positive, for example, developed in late 1984/early 1985 out of an original Terrence Higgins Trust support group for people who had been diagnosed seropositive through the newly available blood test for antibodies to the virus.

There was voluntarism and self-help at the center, but this was also a strongly local response. Early research on policy development at the local level stressed the important input of voluntary organizations.[14] There was a network of locally based groupings of gay men organizing round the disease, often developing from existing gay organizations. There were local groups establishing helplines, calling meetings, trying to obtain funding, in Cardiff, Bristol, Cambridge, Brighton, Exeter, and elsewhere, most arising spontaneously in order to develop a response to the potential crisis. In Cardiff, for example, an AIDS helpline was established in 1984, based on existing telephone counseling which had been run by a local gay organization, Cardiff Friend, since the mid-1970s. The local presence of prominent gay academics and good links with the health authority ensured a relatively swift response.[15] In Brighton, what later became the Sussex AIDS Centre developed out of a Body Positive group and the local gay helpline. Initially it had no premises, but had the use of the local Family Planning Association's telephone and offices three nights a week.[16] The Family Planning Association Regional Manager began giving AIDS information from the Family Planning Office in 1985 on his own initiative. The same picture emerged across the country, of local gay groups organizing on a self-help basis, as one person put it, "groping in the dark," developing information and advice services in a vacuum.

Although many of the early AIDS activists in London, in the Terrence Higgins Trust, in particular, had a history in the gay liberation movement of the 1970s (leading subsequently to media accusations that gay activists were using AIDS to develop a specific gay political agenda), AIDS had a unifying effect, bringing together a wider range of gay volunteers than had been involved in gay liberation. It drew on the strand of consumer-oriented gay men who had become increasingly important in the 1980s. Groups such as Crusaid, a voluntary organization established in 1986 to help, fund, support, and care for people with AIDS and HIV, drew on the support of gay men who were not activist in any political sense, but who had equally developed a sense of community.[17]

The gay volunteer response was thus more than just a political one. But its political

dimension was also highly significant. Although this was a phase of pure voluntarism, an embryo relationship with the state was also beginning to develop. Indeed, this was part of the revised strategy of activists in the Terrence Higgins Trust; policy input was vital, along with a stress on the heterosexual nature of the pending epidemic. Gay AIDS volunteers, in particular in the Terrence Higgins Trust, were part of the emergent AIDS policy community of AIDS experts and civil servants from within the Department of Health. Tony Whitehead, for example, Chairman of the Trust Steering Committee, along with other gay volunteers, had meetings with Sir Donald Acheson, Chief Medical Officer for Britain, in 1984 which led to initial funding for the Trust. Informal links continued; and a number of gay men were represented on the Department of Health working group on health education which began its meetings in 1985.

This type of relationship opened up possibilities of policy influence—but it also led to tensions within the political wing of the gay organizations. The differences were over the classic voluntary/state issue—did potential cooperation with the state actually mean potential cooption and incorporation? Would community organizations simply come to do the bidding of the state? These types of debates were particularly acute in the gay organizations, where AIDS had been seen initially by some activists as a media-induced panic, which could potentially bring in its train the remedicalization of homosexuality and a reversal of the advances made by gay liberation in the 1970s. On the one hand gay politicians such as Tony Whitehead selfconsciously adopted a "Broad Church" approach, forging alliances with groups outside the gay nexus. On the other, the separatist wing, represented in particular by the Switchboard volunteers, remained deeply suspicious and hostile to the compromises in gay identity which were thereby imposed.[18] "We musn't forget the extent of self-censorship that was imposed . . . we had to sit in meetings and pretend that we weren't gay people . . . the Trust was not presented as an explicitly gay organisation. . . ."

Nor was AIDS confined to the gay community. There was also a broad mobilization of volunteers from rather traditional British voluntarist backgrounds. These ran local helplines and rallied to other AIDS organizations from around 1985 onward. This was a mobilization outside the gay community. One drugs worker recalled the Women's Royal Voluntary Service running a pioneer mobile needle exchange in Southend.[19] In Cambridge, a worker on a local AIDS program recalled that the main problem among volunteers was not burnout but demoralization. "The problem was that all those people had been trained and there weren't any sero-positive people to support."[20] In Cambridge, as in Exeter and elsewhere, energies were turned instead into general consciousness raising, with talks to Women's Institutes and an emphasis on educating key gatekeepers of funding about the condition.

AIDS thus created a new voluntary sector specifically focused round the disease and its ramifications. But it also intersected with other and older models of voluntarism. The issue of AIDS, blood products, and the blood supply—which first became current in 1983—and the question of possible transmission of the virus into the general population via injecting drug users, which came to public attention with the discovery of the virus among a group of users in Edinburgh in 1985—brought other voluntary organizations into the AIDS arena. The Haemophilia Society and SCODA (Standing Conference on Drug Abuse), the network organization for the drug voluntary sector, also became involved. Here were established groups that were very different from each other and from the gay AIDS organizations and which also had their own agendas. The Haemophilia Society, for example, was a long established organization, in existence since 1950. It had had a paid secretary since the 1970s and a paid AIDS coordinator since 1987.[21] Its ethos of voluntarism was quite different from the activism of some of the gay organizations. AIDS was not its primary focus; the AIDS obit-

uaries (often not acknowledged as such) sat oddly beside reports of jumble sales and caravan holidays in the Society's newsletter.[22] The Society, despite the enormous impact of AIDS on its work and focus, in particular through the struggle for compensation, remained primarily, as one worker put it, "a haemophilia organisation, not an AIDS organisation." The Society's initial response to the threat of AIDS in 1983 was to urge hemophiliacs to continue to use blood products; the threat of AIDS was regarded as less than the impact of discontinuing treatment. Its campaign for compensation, begun in 1987, was ultimately effective. But its members did not have a collective identity comparable with that of the educated articulate urban professionals of the London-based gay organizations.[23]

For the Haemophilia Society the issues were the safety and quality of blood products; and the safety of the blood supply. It initially found it hard to be linked with a gay organization which was primarily concerned with issues of sexual transmission. It was what one worker in the Society called a "bizarre and unusual situation" with relationships of "mutual suspicion" (which he was at pains to stress had subsequently been modified). The image of AIDS as a gay plague contributed to the Society's difficulty in dealing with it. Members' sensibilities demanded that initially HIV/AIDS information be given separately from the main Newsletter and *Haemofacts* was published from 1984 to 1987.[24]

The links between SCODA and the gay voluntary sector were easier to forge. SCODA itself was an established organization with paid workers and developed skills in parliamentary lobbying (its Director, David Turner, was assistant secretary of the All Party Parliamentary Group on Drugs). There were also personal links between workers at SCODA and at the Trust, between gay men in both organizations. Bill Nelles, a drugs worker initially employed by SCODA in 1985 to produce a leaflet on AIDS for drugs workers, subsequently moved to the Terrence Higgins Trust in 1986. The Trust's development of its own drugs work later proved controversial. The drugs voluntary sector, which had become increasingly important in the policy and service response to illicit drugs in Britain since the 1970s, began to discuss the issues raised by AIDS. Harm minimization and the possibility of condoning injecting drug use forced some harsh reappraisals of the abstentionist policies of the drug rehabilitation communities.[25]

Another area of strong existing voluntarist endeavor, the hospice movement, had a complex reaction to AIDS. Hospices, providing terminal care primarily for cancer patients, had burgeoned rapidly in Britain in the 1980s, mostly outside the National Health Service (NHS). Fundraising and volunteering at the local level for the local hospice was reminiscent of the strong voluntary input into and support for local hospitals both prior to and after the establishment of the NHS. This was an area of voluntarism which had to some extent been undermined by the establishment of large district hospitals, remote from local interest. Hospice support had replaced hospital support. Here, AIDS provoked a varied response. The most public face of the movement led by Cicely Saunders, a hospice pioneer, opposed extending hospice provision for AIDS patients. There were a variety of reasons—the impact of young, perhaps demented patients on primarily elderly cancer sufferers; pressure on beds; and crucially, the voluntary dimension. There was concern that local funding might dry up if hospices were seen to be "taken over" by a stigmatized group very different from what Dame Cicely called "our usual group of patients."[26] However, this was always the view of a minority; a more common reaction was that a local hospice would take on AIDS patients if asked to do so.[27] Many such as the Princess Alice Hospice in Esher subsequently did, without losing local income or support. A specific AIDS-related hospice movement also developed; the Lighthouse in Notting Hill did encounter strong initial local opposition, but subsequent to its opening in 1988 involved a wide range of community support.[28] Hospices like

Lighthouse, and other AIDS health centers such as the Landmark in Brixton in South London, came to act both as day centers, and to pioneer "joint working" between health authority, local authority, and volunteer input.[29]

The initial stage of reaction to AIDS was thus marked by a vitality from both new and old voluntary organizations. A particular AIDS voluntary ethos established itself. In the newer gay-dominated voluntary sector, this ethos placed strong emphasis on overtly democratic internal procedures giving full weight to the role of voluntary workers and, in particular, to the primary role of people with AIDS (PWAs). For example, until 1992, eight of the nine directors of the Terrence Higgins Trust were reelected annually by a constituency of the organization's volunteers. Three of the eight were elected by "privileged" volunteer groups, the early pillars of the organization. For Frontliners, the organization for people with AIDS, the main qualification for Board membership was an AIDS diagnosis. The issues this raised for the development of the AIDS voluntary sector will be discussed below. The ethos of democracy and the primacy of PWAs was not totally monolithic; and there were variations among organizations. One gay man with AIDS recalled:

> In 1987 I came to London and got active in Body Positive. It was an enormous help when I was first diagnosed. . . . After a while, though, I found it a bit too 60's-ish supportive. Everyone was being nice to everyone. There was a lot of relentless smiling and alternative therapies on offer—I was fighting off chiropractors. It was a bit too introspective and wimpy—so I moved over into the Trust.[30]

National Coordination and the Voluntary Sector

The embryo relationship between the AIDS voluntary sector and government and between the voluntary and statutory sectors developed further during the phase of AIDS as war-time emergency from 1986 to 1987. But this phase also showed some of the tensions in the relationship with government; and tensions within the new AIDS voluntary sector. Despite the ultimate success of that sector in pressing AIDS as an issue as one of central governmental concern, this period also gave rise to the increasing marginalization of the original AIDS voluntary sector from central policy concerns.

One issue which embodied the tensions in the voluntary/government policy relationship was the AIDS leaflet which the Department of Health proposed to send to every British household in late 1986 and the subsequent establishment of the National AIDS Helpline. In the autumn of 1986 central government took AIDS as a clear political priority. AIDS became a national crisis, distinct from the departmental issue which it had been before. The emergency debate in the House of Commons in November 1986, the establishment of a Cabinet Committee on AIDS chaired by William Whitelaw, then Deputy Prime Minister—all were evidence of a strong degree of political concern.[31] This rise in the political temperature was marked by a decision to mount a national television information campaign on AIDS, accompanied by a leaflet delivered to every household in the country. Members of the Gay and Lesbian Switchboard and others from the gay voluntary sector, who were involved in meetings about the leaflet in November 1986, strongly objected to the use of the Switchboard number on the leaflet—but with no consultation on its contents. Switchboard and the Terrence Higgins Trust, which was also consulted, were concerned that a national telephone counseling facility be provided. The potential weight of calls to the two volunteer helplines, both on the same exchange, one of the oldest in London, could have blocked out the whole

exchange. Out of this concern came the decision to ask Broadcasting Support Services (BSS) to run a National AIDS Helpline. BSS ran a regular telephone support line across the four television channels, sending out leaflets or answering specific questions in relation to particular programs. In November 1986, Radio One ran an "AIDS week" phone-in organized by BSS; and this model was used as the basis for the National AIDS helpline, funded by the Department of Health.

Telephone counselors were hastily recruited and trained in the period between late December and February, when national AIDS week would take place. With hindsight, members of the gay AIDS voluntary sector saw the establishment of the helpline as a crucial watershed, symbolizing the marginalization of the pioneer voluntary sector. Counselors were trained to talk to anyone—the "worried well," parents, and others—rather than specifically to gay men. A decision was taken to pay them; and many of the counselors from the Terrence Higgins Trust and Switchboard moved over to the Helpline. Mike Rhodes, a Gay Switchboard volunteer, saw it as "a terrible, terrible mistake . . . a lot of people used it as a way of earning a living. We lost all our unemployed volunteers at Switchboard and we've got gaps on our day time rota which we haven't filled."[32]

The establishment of the National AIDS Helpline symbolized the dilemma for the AIDS voluntary sector inherent in this period of national emergency. The heightened awareness of AIDS as a policy issue, the increased funding and government involvement that that brought, also led, apparently inexorably, to both the "de-gaying" of the disease and to the marginalization of the original voluntary impulse.

The issue of national coordination and the establishment of the National AIDS Trust in 1987/1988 emphasized this process. The war-time mood of 1986-1987 naturally led to demands for national coordination, for the linking of both voluntary and statutory sectors to combat the threat of epidemic disease. This was a demand which came strongly from within the gay AIDS voluntary sector. The Terrence Higgins Trust, in its evidence to the House of Commons Social Services Committee which held hearings on AIDS in the spring of 1987, urged that a national coordinating body be set up to bring together both sectors.[33] Professor Michael Adler, a genitourinary medicine consultant who was an important member of the AIDS policy community, initially supported this demand in his written evidence to the Committee.[34] But there was some confusion about who was to do the coordinating. "There were different knots of people in different parts of the forest," recalled one participant. A proposed coordinating organization to bring the different knots together was the United Kingdom AIDS Foundation, which had as its chairman, Sir Gerard Vaughan, a former Conservative Minister of Health. Vaughan was publicly quoted as advocating testing, in particular for immigrants from Africa.[35] Margaret Jay, another supporter, had produced a This Week documentary television program in October 1986 which had raised issues of testing and of notification of the disease, both of which were anathema to the gay voluntary sector. The embryo AIDS Foundation rapidly fell apart.

But out of this debate came a modified form of coordination. People from one knot in the forest went to see Norman Fowler (then overall Minister at the Department of Health and in charge of AIDS strategy), and urged him to bring such a body into being. "We were knocking at an open door. . . . Fowler banged heads together and various aggressive players were removed."[36] Tony Whitehead, then chair of the Steering Committee of the Terrence Higgins Trust, remembered a meeting in 1987 called by Norman Fowler at the DHSS with representatives of the Trust, Body Positive, Crusaid, the DHSS AIDS Unit, Sir Donald Acheson, and Tony Newton, then Minister of Health. In his view,

> The overt agenda of this meeting was to co-ordinate the many services that were developing, and formulate an effective national plan for dealing with AIDS. The hidden agenda of this meeting was how the government could get away with spending as little as possible. It was quite clear that the government wanted to get as much money from the community as it possibly could in order to reduce its own level of funding. It was also clear that it wanted to keep itself as far away as possible from any closely targeted education towards gay men and drug users.[37]

Whitehead's suppositions appear to have had some substance. As a senior civil servant recalled, "the government wanted to get out of things . . . there were a raft of reasons for having a body outside government. . . . There had to be a respectable out for government."[38] The United Kingdom AIDS Foundation had originally been envisaged as the vehicle of this respectable out. Subsequently the strategy encompassed the formation of two organizations, the Health Education Authority, and, for the voluntary sector, the National AIDS Trust. The Trust, with a brief to fund and to coordinate the voluntary sector, was announced in 1987, but was not operational until 1988. It had Margaret Jay as its first director. Robert Maxwell, the newspaper proprietor (employer of Jay's ex-husband, Peter Jay, the former British ambassador to the United States), was quietly encouraged as chief fundraiser. But the Trust was primarily funded, at least initially, by the Department of Health. Maxwell's fundraising efforts foundered in circumstances which led to acrimonious exchanges between the rival stables of newspapers run by Maxwell and Rupert Murdoch's *News International*.[39] The new Trust had a very different ethos to the earlier self-help image of AIDS voluntarism. It had a complex set of advisory committees reporting to a Board of Management chaired by Sir Austin Bide, a former chairman of the pharmaceutical company, Glaxo. The Trust epitomized the involvement of the "great and the good" in AIDS. "It's all become much more mainstream," commented a participant.[40]

Government support for the notion of national coordination was otherwise limited to reluctant support for the AIDS Control Act of 1987, which was in fact the initiative of a Labour Member of Parliament Gavin Strang, member for an Edinburgh constituency. Despite its draconian title, the Act actually aimed to establish the type of coordination between health and local authorities and the voluntary sector, which had long been an aim in British health policy. It required Regional Health Authorities, District Health Authorities, and Scottish Health Boards to give accounts of AIDS control activities in their areas. In practice, however, the annual reports tended to look at health activities and little else.[41]

Even within the gay voluntary sector, the idea of coordination proved controversial. The Terrence Higgins Trust's involvement in moves for national coordination was seen by some of the local AIDS groups as empire-building, the opportunism of a London-based organization aiming to assume a national role. These tensions emerged in other moves to develop a national coordinating organization for the AIDS voluntary sector. In June 1986, a meeting of twelve local AIDS helplines failed to set up a network coordinating organization. The attempt was resumed in 1987 in conjunction with the newly established Health Education Authority and the National AIDS Helpline, which had also started work on a helpline conference. By September 1987, when a second national conference of AIDS voluntary organizations met, the impending establishment of the National AIDS Trust gave the proceedings an air of urgency. Adam Christie of Pennine AIDS Link urged voluntary organizations in the AIDS sector to come together to present a national profile similar to Mencap or Age Concern. "If this meeting does not grasp the nettle, then the voluntary sector is likely to

have a national organisation foisted upon it 'from above'. . . we must move swiftly if we are to be served by an organisation which is our own and over which we have and retain control."[42] Regional and national levels of organization were suggested; the national body would employ a director. A working party of this with the acronym SCONAN, subsequently SCOAN (its terminology modeled on SCODA, the drug voluntary sector coordinating organization) was set up.[43] This eventually transmuted into NOVOAH, the national organization of HIV/AIDS voluntary sector workers.[44] But NOVOAH had a chequered history, bedeviled by suspicions and tensions within the original AIDS voluntary sector. A gay man who went to a later national conference (in 1989) recalled, in an interpretation in part borne out by the transcript of the meeting:

> The conference was excruciating . . . it was in Birmingham. . . . There were blank spots on the agenda or timetable—they were for "networking". . . . There was a messianic figure as chair but no-one knew where they were going. . . . NOVOAH was very resentful of the Trust. . . . There were arcane discussions about the composition of the management committee. They didn't want the Trust (Terrence Higgins Trust) to boss them about . . . . There were personality clashes; there were doctrinal differences between different groups.[45]

The simple demand for national coordination thus proved more complex for those involved than they had realized in raising it. The period of national coordination and national emergency left the voluntary sector in a more complex position than before. Government had grasped the nettle of responsibility for AIDS. But at least three levels of voluntarism resulted: a government funded and linked non-gay AIDS voluntary sector; a largely gay voluntary sector, also receiving government funding, but increasingly remote from the corridors of power to which it had temporarily had access; and a locally based AIDS voluntary sector which retained its original volunteer purity, but at the expense of political impotence and a lack of a sense of direction. In the period after the war-time crisis phase, further complexities emerged.

"Bureaucratic Voluntarism": The Normalization of AIDS, 1988 Onward

From late 1987 to early 1988, the mood of national coordination disappeared. The original policy community alliance of the gay voluntary sector, clinicians, and scientists had peaked in 1986-1987. The mood of coalition subsequently died away. Michael Adler, a leading figure in the alliance, a non-Executive Director of the Terrence Higgins Trust, had dropped his initial demand for national coordination by the time the House of Commons Social Services Committee came to make its final report in 1987. A third stage of AIDS policy making, one I have characterized elsewhere as the normalization of AIDS began in 1988.[46] For the voluntary sector, this can be described as a period of "bureaucratic voluntarism" or "hybrid voluntarism." The earlier ethos of pure self-help gave way to a blurring of the boundaries between voluntary and statutory, and a perceived marginalization of some of the earlier volunteers and voluntary groups. The National AIDS Trust, under discussion in 1987, was operational in 1988 and this symbolized the establishment of a mainstream AIDS voluntary sector. The availability of central government funding and the location of paid posts in both health and local authorities encouraged the professionalization of some of the early volun-

teers. In 1989, British District Health Authorities were instructed by the Department of Health to appoint HIV prevention policy coordinators, focusing on joint health authority, local authority, and voluntary sector strategies for HIV prevention. At the same time the Department's AIDS Care Support Grant to local authority social services (subsequently extended by David Mellor and then by Virginia Bottomley, as Ministers of Health), encouraged the establishment of AIDS posts in local government. In 1991/1992, contributions to local government totaled £10.2 million.[47] This built on the work of pioneering local authorities, Hammersmith and Fulham, for example, or Kensington and Chelsea, which had early on, before the advent of ring-fenced funding, developed AIDS work.[48] The growth in paid posts was significant. The sudden influx of funding, alongside other initiatives, could lead to a bewildering proliferation of posts. In Haringey, for example, the local HIV coordinator working in the local authority HIV/AIDS Unit liaised with a health prevention team led by a separate District Health Prevention Coordinator. A separate Drug Advisory Service was led by a Drugs Coordinator.[49] But the new HIV workers were in a sense acting as professional volunteers. Many were on short-term contracts and had moved over from jobs or volunteering on helplines and in other AIDS voluntary organizations. They developed their own professional networks; and NAHAW (National Association of HIV and AIDS Workers) began to hold its own national conferences to bring these workers together.

The moves toward establishing the purchaser/provider divide and toward contracting out services in the wake of the NHS reforms, and especially through the implementation of the NHS and Community Care Act of 1990, were also perceived as blurring the boundaries, not just for the AIDS voluntary organizations, but potentially for the voluntary sector as a whole.[50] Some AIDS voluntary organizations that had had national funding (Department of Health Section 64 money and the AIDS Support Grant) had to move toward approaching a plurality of funders at the local level. From the viewpoint of the impact on the nature of voluntary effort, there were fears that the voluntary sector would be drawn into a closer relationship with statutory purchasers, providing basic services and with a potential loss of the crucial advocacy role in stimulating change. Some boroughs had adopted this model even before being instructed to do so by central government. Kensington and Chelsea, for example, while early on in 1986 establishing its own AIDS coordinator post with funding from the Sainsbury Trust, also had a preexisting policy of keeping its services to a minimum and funding the voluntary sector to complement them; its funding of London Lighthouse, the hospice and day center for people with HIV and AIDS, was in this tradition.[51] The Landmark in Brixton was another early example of this hybrid voluntarism mingling statutory funding and voluntary input. But the mixed economy of care stipulated by the 1990 NHS and Community Care Act took this model further toward the provision of core services.[52]

Volunteers had thus moved over to become professionals; and the voluntary sector moved into a closer relationship with the statutory. In terms of the power relationships within organizational networks, the impression is that AIDS voluntary organizations drawn into such arrangements became relatively powerless. A director of public health in a regional health authority commented, "We try to institutionalise pressure groups and tame them, although we have to some extent accepted what they tell us."[53] This impression was confirmed by research on the local NHS response to AIDS, which found that voluntary organizations were not influential locally at a formal statutory level.[54]

The advent of changed relationships and increased funding also led to strains within organizations. The move from self-helping to bureaucratic voluntarism brought problems of internal management for AIDS voluntary organizations. Those of the Terrence Higgins Trust were well publicized, both by its own ex-workers and by the media.[55] The Trust's

management difficulties were not unique. The influx of central and other funding into the AIDS arena from 1987 onward brought problems that were well known to any fast expanding voluntary organization. Positively Women, an AIDS charity, began in 1986 in a classic self-help way. Two seropositive women put stickers in phone boxes asking others to contact them. The organization underwent rapid expansion from 1988 onward. A member of the management committee recounted the problems in management terms this brought for a voluntary organization:

> We've had massive change and expansion—a staff of ten now and rising. We've got huge premises and a vast number of different funders. We've had all the problems of fast expanding organisations, chickens before eggs, salaries paid before pay scales, a lack of policies and the management committee lagging behind developments.[56]

There were also problems peculiar to AIDS organizations, and which were highlighted by the collapse in 1991 of Frontliners, a self-help organization for people with AIDS, established in 1986 as an offshoot of the Terrence Higgins Trust. A Department of Health report on the collapse instanced three key factors in the closure—a lack of relevant management experience; the rapid expansion of the organization; and its transition from self-help to service provision.[57] But there were other issues which made AIDS voluntary organizations different. Here the report touched on the problem of the periods of illness suffered by leading voluntary personnel and issues specific to the gay-based voluntary sector—the networks of sexual relationships between participants and the gay liberation agenda. The organization had been forced, it argued, to rush through several stages of growth:

> Due to its rapid growth Frontliners found itself in the position of trying to evolve from "birth" to "maturity" by rushing through the learning stage of "childhood" and by missing out "adolescence" altogether. It is as though the organisation were forced, by the expectations of both members and funders, to run before it could walk.[58]

Despite these well publicized debacles, and the blurring of statutory/voluntary boundaries, the voluntary sector in the AIDS arena remained active and lively in the early 1990s. One survey instanced fifty or so projects working on HIV/AIDS to a national brief, and four hundred other organizations across Britain working in this area.[59] There were the gay pioneers—the Terrence Higgins Trust and Body Positive, but also the subsequent involvement of the generalist voluntary sector. Both Citizens Advice Bureaus and the children's charity, Dr. Barnardo's, developed AIDS-related work, the latter focusing specifically on women and children affected by AIDS. The Voluntary Service Council also established an HIV/AIDS Unit.

Diverse tendencies characterized AIDS voluntarism in the early 1990s. Some agencies were moving towards new and redefined roles in the light of the required contractual relationships with statutory funders, whereas others operated still within traditional patterns. In London, the voluntary sector, determined to remain distinct and unincorporated, also began to organize itself collectively on a more professional basis. The London AIDS voluntary organizations set up a consortium in 1992 which, it was envisaged, would work to negotiate a common minimum data set with purchasers, provide cross-organizational support in the development of monitoring and quality assessment procedures, and develop a common basis

for unit costing volunteer provided services. It was intended as "a collective voice vis-à-vis the statutory sector."[60] For the country as a whole, professionalization was less advanced. A survey published in 1991 found a much more traditional picture. Over one-third of organizations had no paid staff at all. There was lack of collaboration between voluntary agencies both in the HIV/AIDS arena and with the rest of the voluntary sector. Burnout was a problem, but so, too, was boredom, especially for telephone helplines, where volunteers were trained but few people rang.[61] Volunteers disliked fund raising—but that was how many of them were used, shaking collecting tins in a very traditional volunteer way. The picture in the early 1990s therefore remained a complex one at a time of flux in voluntary sector funding.

Issues for the Voluntary Sector

Spencer Hagard, formerly a District Medical Officer in Cambridge, and subsequently the first Chief Executive of the new Health Education Authority, declared in his opening speech to the AIDS helpline conference in 1987 that,

> The voluntary response to the social crisis presented by the arrival of HIV infection provides a unique object lesson in that the speed with which organisations have been conceived and born, grown and come to maturity clearly reflects the speed with which the crisis has developed. . . . In five short years, voluntary organisations have grown to a position not achieved by others over a much longer period.[62]

Others argued, in contrast, that the Thatcher government of the 1980s, with its rhetoric of voluntarism, had in fact presided over the abolition of the voluntary sector. The history of AIDS and voluntarism shows how lively the ethos and practice of voluntarism was and is, albeit within a framework of increased state dominance and new forms of relationship, through contracting, between voluntarism and the state. Nonetheless that history has raised issues and tensions both specific to AIDS, but also to the voluntary sector as a whole. There were the conflicts between the need for formal organizational structures and the activism and commitment which originally brought volunteers together on a self-help basis. This tension has been apparent both within national organizations, for example, the Terrence Higgins Trust, but also at the local level. One of the original volunteers at what subsequently became the Sussex AIDS Centre in Brighton commented,

> The self-help initiative got lost in organisational growth and ceased to be about emotional support. Now various groups meet but HIV is no longer enough to have in common as it was five years ago (1986) when positive people had to rely on themselves. Now there are plenty of people to help which has eroded self-help.[63]

Coupled with this polarity between activism and organization was a tension between voluntarism and professionalization, which, as this paper has demonstrated, was the general tendency over time across the AIDS voluntary sector. The original volunteers tended to become paid professionals. But it was also a tension within organizations, in particular, the new gay-based AIDS organizations where the emphasis on overtly democratic procedures exalted the role of volunteers in contrast to the subordinate position of paid staff. The role

of the PWA (person with AIDS) as volunteer had a particular status. "There's the PWA as hero bit in AIDS—it's like the sanctity of disease in some Arab tribes. . . . There are AIDS groupies . . . some people want to sit at the feet of these sages."[64] Part of the move toward management procedures and structures was an attempt to resolve the imbalance in some organizations between volunteer direction and the role of paid staff, while at the same time maintaining the volunteer enthusiasm and involvement which had initially created the organization. The strategy was one which aimed to balance altruism and professionalism, and the tensions inherent in that relationship.[65]

Service delivery was another issue, again in implicit conflict, or so it seemed, with the early activism and the gay liberation origins of some of the initial volunteers. Tony Whitehead articulated this dilemma in a speech at the International Conference on AIDS in 1988.

> Instead of getting up and banging the table at those meetings as we should have done, instead of pulling the rug from under the government, we said, "Yes, we must do something. We must strengthen the voluntary sector. Yes, we will do all we can to work with you". . . . The work that the gay community has done in fighting section 28 of the 1988 Local Government Act has not been paralleled by any kind of direct challenge to the inadequacies of AIDS funding and government policies. . . . Our immediate response to the tragedy of AIDS has been to rush off to hold people's hands at bedsides. We have not taken our fight out onto the streets as has happened in the United States . . .[66]

Other early volunteers had conceived of a type of radical "rainbow alliance" around AIDS, building on the Greater London Council-based political culture in which some were already experienced. But this was not an overt feature of early AIDS voluntarism, where the provision of services such as buddying, counseling, even financial help, came to predominate simply because they did not otherwise exist. The danger was, as always, of reliance on voluntary groups to provide services instead of confronting those issues in the statutory sector, a danger which the community care changes also pressed upon the AIDS voluntary sector.

Other conflicts arose through the rapid expansion of that early voluntarism—there were tensions between national and local organizations and different models of organizational development. Body Positive, for example, established a loose federation of local groups with local autonomy. The local AIDS helplines by contrast, as indicated by their 1987 conference, resented the perceived claims of the Terrence Higgins Trust to establish itself as a national umbrella organization instead of just one which was London based. Tensions between generalism and specialism also occurred. The early organizations were either explicitly or implicitly, gay based, subsequently expanding (in part because funders wanted them to) to take on a "general population" role; the Trust took on drugs as an issue, and subsequently an appeal for HIV-positive Rumanian babies, both with unhappy results. But other more specialist groups also developed—Positively Women, for example, Mainliners for drug users, Blackliners for black people—and there was, on occasion, hostility between the established organizations and new ones coming in.

S. Kobasa, in a study of AIDS volunteering in the United States, drew attention to the classic tension—which also affected AIDS organizations in the United Kingdom—between social movement and institutional activities.[67] Only ACT-UP, as an unambiguous social movement (and it was less significant in the United Kingdom than in the United States)

avoided those institutional tensions. Incorporation by government in terms of financial support in 1987 and subsequently necessarily led to moves away from activism.[68] For the United States, Kobasa saw this as in some senses a positive process, bringing in its train more involvement in the policy process and greater cohesiveness, despite an increasing dependence on government. The British story was in some respects different. The involvement of the initial voluntary sector in the policy process (however limited and imperfect that involvement was considered to be) came prior to the advent of major government funding. The general population strategy of the war-time like response of 1986-1987 owed much to pressure from, among others, the AIDS voluntary sector. Subsequent funding brought lesser, not greater, policy involvement and the establishment of an official voluntarism that in some senses took on the mainstream policy role.

A New Phase: The Revival of Voluntarism and the "Regaying" of AIDS?

The contract culture of the 1990s was seen as a new departure for the voluntary sector in general. Other changes affected the HIV/AIDS voluntary sector specifically. The announcement in 1993 of the capping of governmental funding under section 64 funding had implications for the larger HIV/AIDS organizations; and the phasing out of earmarked AIDS funding from 1994 threatened smaller bodies. Questions of financial stability and maintaining momentum increasingly preoccupied the HIV/AIDS voluntary sector.[69] At the same there was a sense of "coming full circle," an attempt to revive the earlier spirit of voluntarism and to recreate the effective self-helping strategies of education and information dissemination of the early years. This found expression in moves, from 1992 onward to "re-gay" AIDS. In that year, the gay men's advisory group of the Health Education Authority resigned and reformed itself as Gay Men Fighting AIDS (GMFA), a body which aimed to develop effective peer education strategies, rather than relying on government sponsored agencies. GMFA activists argued that national health education had effectively ignored gay men, and adopted general population approaches to the detriment of the gay community, where most cases were concentrated.[70] Gay organizations such as the Terrence Higgins Trust had disguised their origins in order to win government financial support. "Re-gaying" arose out of a sense of the policy impotence to which this paper has drawn attention. It drew on a powerful alternative official history of those early years of policy input, a history which presented a myth of a unified gay movement and ignored the tensions, disagreements, and denials which also went into that response.[71] New voluntarist initiatives emerged in the mid-1990s, in particular, the Stop AIDS London project which used peer education and outreach strategies for gay men. But history, although mythologized, could not be repeated. The new strategies were locally based and dependent on Regional Health Authority funding.[72] They also promoted a particular London-based gay culture which some gay organizations outside the capital found inappropriate.[73] The tensions between London and the provinces operated in the 1990s as they had done in the 1980s.

"Re-gaying" revived the earlier spirit of voluntarism, but, in its dependence on statutory funding and support, it also underlined the changes which had taken place in the role of the voluntary sector since those earlier days. In general, in Britain, AIDS had demonstrated the strengths of the voluntary tradition. But it also emphasized the complexity of the relationship between voluntarism and the state. "Unambiguous voluntarism" to "bureaucratic voluntarism" was the general tendency. But this implicit progression also masks a period of greatest policy impact in the early self-helping phase; and a continuing complexi-

ty of voluntary/statutory relationships within a sector which was highly diverse. The boundary between government and voluntary sector has long been what William Beveridge called a "moving frontier." AIDS has exemplified that historical legacy.

Notes

1. Ann Digby, *British Welfare Policy: Workhouse to Workfare* (London: Faber and Faber, 1989).
2. See G. Finlayson, "A moving frontier: voluntarism and the state in British social welfare, 1941-1949," *Twentieth Century British History* 1(1990): 183-206.
3. These recent developments are surveyed in Jane Lewis, "Developing the mixed economy of care: emerging issues for voluntary organisations," *Journal of Social Policy* 22(2)(1993): 173-192.
4. Barbara A. Misztal and David Moss, eds., *Action on AIDS: National Policies in Comparative Perspective* (New York: Greenwood Press, 1990) and David L. Kirp and Ronald Bayer, eds., *AIDS in the Industrialized Democracies: Passions, Politics and Policies* (New Brunswick, New Jersey: Rutgers University Press, 1992) both make this general point.
5. Mildred Blaxter, *AIDS: Worldwide Policies and Problems* (London: Office of Health Economics, 1991).
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Reversible History: Blood Transfusion and the Spread of AIDS in France

Anne Marie Moulin

The 1992 trial over contaminated blood revealed to the French people, through reports in the daily newspapers,[1] that 2000 persons, nearly half of them French hemophiliacs, had been infected with AIDS through blood and blood products. Infection occurred for most of them during the crucial years of 1983 to 1985. France is the European country that has been affected the most by the AIDS epidemic.

The Contaminated Blood Affair, as it is known in France, has been more than an episode in the wave of lawsuits filed against doctors, following the American example, and more than an episode in the struggle of angry patients against doctors. It has marked a turning point in the status of the medical profession in France, and perhaps the end of its century-old privileged, exceptional status. Four doctors were put on trial, but witnesses came from all social classes. If lawyers and judges referred to highly technical information, this information was explained in such a way as to be accessible to the ordinary citizen, and, in particular, to the hemophiliacs crowding the courtroom. The Affair not only pointed to a failure in the French blood transfusion system, which proved unable to cope with a looming epidemic, but also cast suspicion on medical science and the medical profession, and more generally on the political choices of French democracy.

The trial took place in 1992, before a civil tribunal that was part of the Paris Court of Appeals. It did not take place before a professional medical administrative tribunal,[2] a criminal court, or in an exceptional jurisdiction, but before an ordinary tribunal. Because blood transfusion is a "total social fact," to use the phrase coined by French sociologist Marcel Mauss, the Affair was a "total social fact," a total drama. The trial brought into question convictions which had been shared by most citizens for decades. The French felt that history had not followed the right course, and that perhaps some past choices would have to be reversed, at the cost of finding a new philosophy of history.

The judges indicted four state ministers, as well as medical advisers closely linked to the President of France. The trial, widely publicized, shook Socialist France to its very foundations. The lawsuit took place at a time when the political ideologies of the previous generation were being assailed by doubt, three years after the Berlin wall came tumbling down, and the Old World Order was shattered.[3]

The trial brought into sharp focus the evolution of the relationship between law and medicine. Although ever-increasing medicalization had been considered an ambivalent but inescapable feature of modernity, the public suddenly appealed to the law[4] to oppose the perverse effects of a medical science deprived of morality. This was to reverse the course of what had appeared as a historical necessity. An epidemic reminiscent of ancient pestilences kindled public debate on medical science, doctors, politics, and law. The trial was an illustration of the debate.

The drama, which concluded with the massive infection of French hemophiliacs with AIDS and also of a still undetermined number of people (some say five thousand[5]) infected through blood transfusion, is a short-term event. It began in the summer of 1983, when the risk of infection from transfusion was first publicly recognized, and ended with the official preventive measures of the fall of 1985. As a historian of science who relies on her knowledge of epidemics in the remote past and who has observed for the first time as an eyewitness the course of an unknown scourge and the developments relating to it, I would like in this paper to discuss the long-term consequences of the Contaminated Blood Affair and the reversibility of historical choices.

Transfusion before AIDS

Early blood transfusion was organized in France after the First World War by the hematologist Arnault Tzanck, the surgeon Gosset, and the obstetrician Cohen-Solal, with the establishment of the *Oeuvre de la transfusion sanguine d'urgence*. This was a makeshift center for organizing emergency blood donations at the Saint Antoine Hospital in Paris, where the present Centre National de Transfusion Sanguine is located. Arnault Tzanck, who has been called Mr. Transfusion in France, advocated transfusion with great vigor.

During the Second World War, the hostilities fueled the need for blood transfusion. With the development of Edwin Cohn's method of fractionation of plasma, the demand for blood grew enormously. The battle of Monte Cassino provided the opportunity for the French to develop transfusion, and 15,000 Algerian soldiers were solicited to donate blood. Dr. Benhamou, who had coordinated the transfusion staff in Algiers, organized transfusion in the army.

Tzanck, who had joined the Resistance during the war after exile in Chile, opened the first official course on transfusion in Paris in 1945. Within three months, all the knowledge necessary to become the director of a transfusion laboratory could be acquired at the Saint Antoine Hospital. The foundations of the organization of transfusion in France were laid in an atmosphere of general reconstruction that was part of the post-liberation era. The law that was enacted in 1952 governing transfusion is the same law that has regulated transfusion until very recently. When it was enacted, the law was imbued with the solidaristic and idealist ethos of the time.

The 1952 law established a monopoly on transfusion for so called centers, which were placed under the supervision of the Health Ministry and the Direction Générale de la Santé (DGS).[6] France developed 170 transfusion centers that were very varied in size and status. Some of them were managed by non-profit organizations, some of them were attached to local hospitals, and some of them were independent. Centers could compete with one other. They had financial autonomy, but were accredited and regulated by the Health Administration. The DGS fixed the standard price for the sale of blood products and issued memos. A Consultative Committee for Blood Transfusion (CCTS) performed advisory functions and acted as an intermediary between the scientific community and those providing transfusion. In Paris the Centre National de Transfusion Sanguine (CNTS), a confusing title since the center was Parisian rather than "national," did not exert any authority over centers that were its peers. It ranked first, however, among all the other centers, because of its historical origin, its scientific prestige, and its publication of a volume of transactions. In addition, from 1982 on, the CNTS was given a monopoly on imports of blood and blood products.

The principles of the 1952 law governing transfusion specified volunteer, anonymous

donation of blood, not the sale of blood for profit. The philosophy behind this ideal deserves a brief comment:

(1) During the interwar period, blood donors in France were recruited mainly from those in professions linked with the civil service (the health professions, but also policemen and firemen[7]). Tzanck's *Oeuvre* functioned with a secretary, a telephone, and a list of persons who could be called at any time to donate. Families were also solicited for blood donations in cases of emergency, but it was generally thought that finding donors from within the family could entail psychological problems, some relatives being cowardly or reluctant to confess hidden syphilis. (This strikes a familiar chord.) Hence the attraction of recruiting people as donors who were expected to be healthy and who were altruistically-minded for professional reasons. But the *Oeuvre*'s list also included paid donors who found it expedient to increase their income: students, for example, could find in blood donation an opportunity to earn some money.

After the war, paid donors acquired the reputation of being unreliable on the subject of their medical pasts and unpaid donations became more fashionable. Blood donation was clearly reminiscent of martyrdom on the battlefield. In keeping with this, a 1954 law would subject the generation of 1944-45, which had escaped conscription, to donating their blood as a way to repay their debt to their country.[8] Donation for money tended to encapsulate the hazards of blood exchange, and voluntary blood donation was increasingly correlated with safe procedures.

(2) Anonymous giving, being different from intrafamily donation, suggested a collective phenomenon, a pool of collective blood stored for community needs. Historian of law Jean-Pierre Baud has recently pointed out that such a concept is analogous to the stocking up of merits by the Catholic Church for the sake of all believers, and even of all mankind. He quotes a Renaissance canonist: "and this blood shed by saints and martyrs is a treasure deposited in the Church's coffers the key of which belongs to the Church itself."[9] Holy Communion in the form of bread and especially of wine illustrates the redistribution of this miraculous "manna." The historical irony is that "pooling" of blood is now synonymous with risk amplification when referring to the use of multidonor concentrates of antihemophiliac factors.

Anonymous blood donation carries another meaning: it means, theoretically at least, that all men and women are potential donors or receivers and thus can contribute to a movement of universal exchange. The exchange, however, is restricted by the rules of blood grouping which exclude some types of transactions. The categorization of blood into groups is completely dependent upon laboratory devices, and ignores any concerns about skin color or ethnicity. This was contrary to common practice at the Cook County Hospital in Chicago,[10] when it opened in 1937 as the first blood bank in the world,[11] and was also contrary, until recently, to common practice in blood collection in South Africa. Science thus promotes a rationality of its own, which ignores social classifications and helps to relativize them.

(3) Non-profit donation excludes blood from the commercial sphere. Blood is not merchandise for sale, nor is it even a medicine.[12] For historical reasons (mainly because of the struggle against "secret remedies"), pharmaceutical products have been patentable in France only in the post-World War II era, and blood products have been excluded from this category of products.

It is clear that several contradictory lines of reasoning were entangled in this legal framework:

One line of reasoning was social, with an emphasis on human and social solidarity, all classes and groups combining to face the common hazard of sickness, and on the civic responsibility of donating. This evokes a freely consented-to social contract and is the opposite of the coercion that led the poor to offer themselves as guinea-pigs in the era of the clinic.[13]

The second line of reasoning was scientific, the fact that blood typing cuts across the ordinary frontiers of race, ethnic group, and nation. This point was well established during the First World War, with the first international survey conducted by the Hirszfelds in the multinational Allied army on the Macedonian front.[14] While investigating heredity in intraspecific blood agglutination reactions, Ludwig Hirszfeld first coined the phrase "biochemical races."[15] In 1919, he came to the cautious conclusion that there was no specific marker in the blood coincident with ethnic or racial borders because of relative panmixia and dropped the idea of biochemical races. He contented himself with describing an A/B blood vector that progressively decreased from West to East.

The third was a commercial trend. This went largely unnoticed in the first texts concerning the establishment of transfusion, as, in the post-war era, blood transfusion centers shifted from being small scale "in house" enterprises to being locations of industrial technology and mass production of derivatives. Some centers had industrial installations and could fractionate plasma which they bought from the smaller centers.

The French law of 1952 was inspired by a conviction that donation of blood was a vital gift that demonstrated and reinforced social ties. The transfusion system was considered to be a "fondateur de liens sociaux."[16] The law incorporated basic principles such as the inviolability of the human body and the unavailability for sale of its products. However, these principles were clearly at odds with the actual situation in the transfusion system at the time the law was enacted, when in France, as in all European countries, paid providers outnumbered unpaid donors.[17]

Historian Jean-Pierre Baud sees these contradictions as a consequence of reintegrating the body into the law.[18] According to him, the handling of blood products is not an ordinary activity. Blood has been the subject of multiple taboos in many civilizations. French law, which is derived from Roman law, has, up till modern times, generally ignored the body and its needs, and has dealt only with persons who contract freely with one other and dealt also with their property.[19] Blood is neither a person nor merchandise and, as such, is not easily dealt with by legal rules. The ancient taboo which forbade naming blood led to the adoption of euphemisms with regard to transfusion: blood is neither bought nor sold, but is "deposited" in pharmacies, "delivered in return for payment," or "given for a fee." This embarrassing mixture of charitable and commercial terms reveals a reluctance to admit that, through technical innovations, blood has become progressively estranged from its human bodily source and it dangerously obscures the fact that "red gold" has entered the international marketplace.[20] The ambiguity of the 1952 law avoided the problem of coping with the modifications in blood transfusion required by new biotechnology.

Patent expert Marie-Angèle Hermitte analyzes the situation in strikingly different ways from those of Baud. Instead of a resurrection of an archaic past making room for the body in law, she sees the 1952 law as a transition product, promulgating certain rights in the face of a changing reality.[21] The law put forth principles more like a gold standard against which to assess all measures to come in the future rather than as a code governing existing medical practices. Compensating donors for blood was first suspected and then discarded as potentially dangerous and ethically disputable.

While the nature of the hazards was changing,[22] transfusion was well established as a safe procedure in the public and medical mind and practitioners prescribed blood lavishly.

In some surgical wards, patients were not permitted to leave the hospital unless their hemoglobin ratio reached 14g. France was the leading European country in the collection *and* in the consumption of blood. Although the risk of hepatitis from transfusion was known by this time, blood transfusion was a closed world dominated by hematologists.[23] It offered to those outside a striking example of an activity the hazards of which had been impressively restricted.[24]

Donors' associations played an important political role in France. The Federation of Blood Donors, created in 1946, was very influential. Blood collections were conducted in the workplace, with social pressure being exerted on those who were reluctant to donate. Donors were proud to exhibit their cards. The giving of blood was synonymous with abundant health, and even virility, exuberantly praised in a Mediterranean country. Previously, donors had been associated with scientific ventures. Nobel Prize winner Jean Dausset exploited the volunteer zeal of donors' associations when he needed the cooperation of donors in order to map the first system MAC (the initials of a patient's name), i.e., to screen anti-HLA antibodies. Significantly, when Dausset received his Nobel prize, he took several donors with him to Stockholm.

Donors' associations were not ready to hear about the potential risks of donation, the presumption of morality being assumed on the donors' behalf. Blood donation for money was singled out and blamed for all hazards. In the 1970s, an Iranian movie, *The Cycle*, which appeared in Paris cineclubs, showed destitute people from the Amir Kebir area, a borough of South Teheran well known to hippies, coming to sell their blood with jaundiced faces. As is now known, hepatitis contamination of blood was in many ways a rehearsal of AIDS contamination. But the Iranian case seemed a perfect illustration of the excellence of the French blood transfusion system, which was based on free donation and national self-sufficiency. A report from the French Council of State in 1988[25] said that "the Red Cross and the Red Crescent have chosen it (the French system) as a standard for the countries where they are responsible for organizing transfusion, and WHO (World Health Organization) also refers to it as a model, ready to be made universal."

This self-satisfied mood was widespread, starting at the top. Jean-Pierre Soulier, the authoritative hematologist at the head of the CNTS, writing in 1983 on the eventuality of a contamination, proffered a non-prophetic statement: "while waiting for the discovery of a reliable test, one can speculate that in France, the country of strictly volunteer blood donation, the transfusion risk of AIDS is extremely low."[26]

This statement lumped together scientific convictions with political beliefs: the ideological architecture of transfusion would prevent any moral fault. Transfusers and donors mutually comforted themselves by the statement that donated blood was safe. In his open letter to hemophiliacs in 1983, Director Soulier warned them against extravagant use of the new concentrates of Factor VIII (which were obtained through pooling of blood from a number of donors), but indicated at the same time that any danger came from abroad (the notion of blood for money) and that the donor system in France itself was immune from taint. This was precisely at the time that the stocks of blood in the country were beginning to be massively contaminated.

Irreversible History and Political Choices

When compared to other types of organizations, moralists and politicians could argue that the blood donation system displayed marks of social solidarity as well as those of universal

exchange. In a very stimulating book, British sociologist Richard Tittmuss[27] analyzed the British system of transfusion, which was based on principles analogous to the French system. For Titmuss, a system of unpaid blood donation was ideal from all possible viewpoints. He showed that the gesture of donating epitomized social links and reinforced solidarity, whereas all systems based on transfusion for money were ethically unacceptable and politically damaging, and incidentally could be a source of potential risk for recipients. From Tittmus's book it appears that a transfusion organization can be an excellent indicator of societal and political choices.

Organ and fluid transfer are medical gestures embedded in social practices. Blood transfusion and organ transplantation have a social and symbolic impact that goes far beyond their quantitative presence among medical cures. Transfusion goes back to the seventeenth century, when the first experimental attempts were performed in England. The human application seemed to meet with success and most scholars welcomed the therapeutic innovation. Renaissance individualism had broken the compelling bonds of communities. According to religious reformers, man had to ensure his personal salvation, irrespective of the multiple mediations of the Church on Earth and of saints and angels in Heaven. Transfusion offered an extension of the self-restricted orbit of blood circulation in the isolated body. Transfusion was seen as a means to restore a link between microcosm and macrocosm, a means, in the framework of mechanistic medicine, to initiate a much needed current of exchange and sympathy. I have argued elsewhere[28] that transfusion (and transplantation) compatibility includes not only a biological component, but also a social one that has to be taken into account. This cultural compatibility is subject to change. This explains why an appeal to the law is not necessarily made, even though the law provides grounds for accusation.

In 1986, I attended a conference at the Massachusetts Institute of Technology, at which Harvey Sapolsky spoke.[29] He explained that a commission had examined the alternative options for the organization of American blood transfusion, such as reverting to blood banking as originally planned, with savings and credit cards, autotransfusing, and intrafamily donation (*transfusion dirigée*). After his discussion, Sapolsky concluded by saying that, because the whole idea of unpaid donation of blood had been so entrenched in our minds for half a century, it was impossible to break with the tradition. And it is true that, in the 1980s, if a patient, checking into a clinic, asked to deposit his own blood in advance or to bring his own personal set of donors, he might be severely rebuked. Nevertheless, following the shock of the transfusion scandals, autotransfusion (before or during the operation) has developed in an explosive manner, thus falsifying Sapolsky's statement. Far from being irreversible, history is reversing itself.

The argument of historical irreversibility has been discussed in another tragic context. The extensive use of new technology has enabled hemophiliacs to lead a normal life, including being able to play sports. When Soulier suggested at a meeting of hemophiliacs that they should limit their use of concentrates, a hematologist protested: "First we treated our patients, then, we progressed to preventive treatment. This is the irreversible march of history. We have opened up the era of prevention for hemophiliacs. The only wise course is to continue the march forward."[30] How to oppose the "irreversible march of history," how to resist the seduction of scientific progress?

If morality and science were on the same side, to take this further, experts in social sciences ventured to say that the unpaid blood donation system was competitive from the viewpoint of cost and efficiency. Although his statistics have been questioned, Tittmuss himself posited the gift of blood as the cornerstone of popular transfusion, being cost-effective and fulfilling medical needs. National self-sufficiency in blood collection was a slogan that com-

bined the virtues of morality and economy, since it meant avoiding spending money on the importation of blood. When Michel Garretta succeeded Director Soulier as the head of the CNTS, he was expected to promote French self-sufficiency, an ideal that could not be fulfilled because of the skyrocketing demand for the new blood products by hemophiliacs. With this in mind, Garretta had a giant factory built for the extraction of Factor VIII, among other blood products. He started to replace the unsafe unheated blood products that came from abroad[31] with French lots (soon to be contaminated). By that time most foreign companies had adopted the new methods of heating for prevention of disease transmission.

In fact, the institution of transfusion in France was more problematic than it appeared. One of the problems, which was linked to its structure, came from an accumulation of functions. France is a relatively small country that is heavily centralized. The transfusion people form a small closed world. In the dialogue between administration and transfusion centers, the same people had positions in both worlds. The protagonists of transfusion were chairmen of learned societies, such as the International and French Societies for Blood Transfusion, they had seats on the Consultative Committee for Blood Transfusion, and they took part in commissions supervising the funding of research. This overlapping of positions made the inquisitive regard of an outsider impossible.

The state health administration was also marked by an overlapping of positions amongst its personnel, an extreme division of labor, and a weakness in its expertise in public health.[32] The ministries relied upon a small group of authoritative leaders who were invested with conflicting responsibilities. Younger academic clinicians[33] had in the early years acted as the avant-garde in the area of AIDS,[34] but their views were not heard in the upper spheres of government. Finally, research and industry operated at a distance both from the hospital wards and from the prescribing practitioner.

Hemophiliacs figure as captive consumers, trapped in the system, often personally attached[35] to their doctors and to the transfusion people. The headquarters of the French Association of Hemophiliacs were located in the CNTS building and the Association could indulge itself in the idea that it was obtaining information from the source. Hemophiliacs could also suspect that those who warned them about the dangers of the new blood products were trying to cut down on expenses.

Contrary to all predictions, history would reverse itself, under the threat of AIDS.

The Three Options: A Blocked Issue

In 1983, it became clear to the international scientific community that blood transfusion was a possible route for AIDS transmission. In August 1982, I was personally involved in the management of a strange "case."[36] A person belonging to my own institution of research was admitted to hospital for unrelenting diarrhea and bouts of fever associated with multiple parasitic and bacterial infections. I was shocked at the insidious cross-questioning he underwent that tried to obtain from him a confession of his homosexuality. This he denied to his last minute. Reality was, in fact, simpler. During field research, he had had a motorbike accident and, as a consequence, he had a limb amputated in . . . Haiti. The risk of transfusion was an acquired datum among clinicians by the end of 1982.

In March 1983, the Centers for Disease Control[37] in Atlanta sounded the alarm of the risk for hemophiliacs of multiple blood transfusions. The risk was confirmed by the United States Food and Drug Administration a month later. Between February and June of 1983, Robert Gallo and Luc Montagnier's reports of LAV and HTLV III established the probability of a viral infection for AIDS.[38]

In 1983, three options were available for prevention of transmission of AIDS by blood transfusion: donor selection, eliminating the virus from blood products, and blood testing. These three options were not explored equally. The drama proceeded in two phases: the first was from March 1983 to January 1985, when the first tests for detecting the virus became available in France; the second was from January 1985 to August 1985, when testing donated blood was made compulsory, and then to October 1985, when transfusion centers were no longer reimbursed[39] for unheated blood products by French Social Security.

Donor selection seemed to be the most effective measure amongst the three, in the absence of a test or a method for inactivating the virus. Selection could be carried out either by personal interview, or by administering a questionnaire. The DGS produced a first circular, in 1983, aimed at all transfusion centers, advising selection of donors in a discreet and tactful way. The circular had little effect, although reactions were very different from one center to another.[40] Organizations were reluctant to see suspicion cast on their "clean" donors and stuck to the dogma of safety through voluntary donation. Questionnaires raised the issue of confidentiality.

In addition, the centers feared that they would be in difficulty because of a shortage of blood and blood products. Depending on the criteria, selection could range from excluding a few very small groups to excluding all groups of high-risk donors, and lead to the exclusion of a high percentage of gifts of blood. Owing to the counterproductive effects of fear and suspicion, the drop in blood collection might be more than one third. Centers would be forced to do what they officially rejected, import foreign blood products.[41] As the fees negotiated by the small centers were proportional to the number of units of blood bought from them, collecting was the most important element determining their margin of profit. Any measure that would discourage donors and thus diminish the amount of blood collected was scarcely acceptable.[42] This explains (without justifying it) why collection was not interrupted in prisons until the beginning of 1985, even though the elevated number of prisoners belonging to high-risk groups was already well-documented.

The dogma of self-sufficiency linked the public powers, the donor associations, and the transfusion directors. Public authorities did not proclaim the risks of transfusion and did not address donors directly.[43] The transfusion centers were more or less left free to select donors using the strategy of their choice and tended naturally, with few exceptions, to choose the strategy that was the least damaging to their financial interests. For sociologist Michel Setbon, a lack of efficiency in donor selection by itself might explain the differences in the numbers of hemophiliacs contaminated in Sweden, Great Britain, and France when the three national administrations were simultaneously aware of the risks of transfusion. A second circular by the DGS in France, in 1985, written in a stern style, chastised the absence of methods of selection of donors by transfusion centers and revealed in retrospect the centers' lack of compliance. This memo was written only after the results from the first serological surveys of blood donations were known.

Some laboratories had started, on a rudimentary homemade basis, to perform tests on their blood samples.[44] Immunologist Jacques Leibowitch prompted his colleague Jean-François Pinon in a Paris hospital to use these in-house tests to screen a donor population. The national epidemiological situation was heterogeneous: there was a veritable abyss between the "hot spots" of Paris and the South of France, and the rest of the country. By the end of 1984, however, with a seropositivity rate in donors of 0.05 percent, according to Pinon and Leibowitch,[45] it could reasonably be argued that all concentrates originating from pooling were potentially contaminated.

The second option for prevention of the transmission of AIDS was the adoption of

heated blood products, once virus inactivation was recognized as effective. In March 1983, the Travenol laboratory offered heated products to the leaders of CNTS. By June 1983, all authorities, scientific and administrative, knew that unheated products were dangerous. However, imports of Hemophil T (T for treated) were limited to those required for experiments conducted to compare heated and unheated products and contaminations were recorded! Clinicians who requested the "good" products for their patients received the reply that such blood products were restricted to patients randomly selected in protocols. Access to heated concentrates functioned as a privilege, contrary to all ethical rules for human experimentation. The negotiations for transferring the technology for heating blood products to the French factories dragged on, owing to personal dissent and financial obstacles.

Because transfusion directors aimed at financial autonomy, they privileged management over their medical vocation. The desire to avoid the enormous financial loss of throwing away the unheated concentrates led to the decision to continue the distribution of the French products, and then, once the massive contamination of French Factor VIII lots was known, to the decision to get rid of the stocks only at the last minute. At a meeting of the National Hemophilia Commission in June 1985, it was said that "an intermediary period . . . where heated products would coexist with unheated products still in stock is acceptable. From now on, imported or French heated products must be specifically reserved for LAV negative hemophiliacs."[46] The stopping of the use of unheated products had been initially planned for July 1985. At a meeting, it was decided, solely for commercial reasons, that the measure would be delayed until October 1. Products returned to Paris by August and September 1985 were even recirculated by the CNTS.[47]

The third preventive option was the application of a test that would pick out the dangerous donors. Transfusion centers were receptive to the idea of a testing procedure as had been the rule for detection of syphilis.[48] From February 1985 on, the DGS officers made it clear that they would prefer a nationally produced test for detection of the AIDS virus. Abbott Laboratories, a United States pharmaceutical company, applied for a license to market its test in France in February, before Pasteur Diagnostics (the marketing arm of the Pasteur Institute) did, but the institute lobbied to postpone approval of Abbott's test by the National Transfusion Laboratory until its own test was ready.[49] François Gros, President of the Academy of Sciences, medical adviser to the Minister of Health, and former director of the Pasteur Institute, asked in May 1985 that the Abbott application be put aside until Pasteur Diagnostics' test was available. The approval of Abbott's test was effectively blocked until the Pasteur Diagnostics' test was ready and it was only finally accorded in July, several weeks after that of the Pasteur Institute.[50] After 1 August 1985, mandatory testing was applied to all blood samples in France. Five months had been lost, however, since the Abbott application had been filed, months that cost human lives.

No French national authority up to that point had proclaimed an "état d'urgence." If the authorities were reluctant to cope with the epidemic at a national level, what about the researchers? Undoubtedly, the description of the AIDS virus by the team of Françoise Barré-Sinoussi and Luc Montagnier, once amplified by Gallo's recognition of the virus's causative role in the disease, played a role in awareness of the epidemic. Individual researchers were puzzled by the elusive signification of seropositivity and hoped that antibodies would be an indication of immunity as well as of infection.[51] It is possible that some of them were even influenced by the idea of a recontamination by vaccination,[52] which had been an unfortunate trend in research on syphilis in the nineteenth century.[53]

In 1987, a national program for AIDS research was launched in France. However, all institutions of research were not immediately enrolled in the struggle against the disease, as

historical research conducted in the INSERM archives shows[54]: fierce competition among researchers and an underestimation of the rate of progress of the epidemic slowed the process. INSERM did not take the lead in a general program of AIDS research, preferring to stick to its usual role of regulating spontaneous scientific activity. The report written by Professor Claude Got for Health Minister Claude Evin remarked ironically that INSERM had forgotten that the "S" in its acronym stands for Santé (Health).[55] Only in 1989, did the foundation of a major national agency in France,[56] the National Agency for AIDS Research (ANRS), independent of the national research centers, testify to a belated vigorous impulse of the state where AIDS was concerned, and crystallized the initiatives of individual researchers in each institution. In the same year, the government made it known that from then on the fight against AIDS was the affair of the state.

The 1992 Trial[57]

In 1988, the first steps were taken for public legal action against the masters of transfusion. Several hemophiliacs or their families were the plaintiffs. The plaintiffs brought a civil and penal lawsuit—for conscious misinformation, for lack of assistance to persons in danger, and for the conscious delivery of unsafe products—based on a 1905 law forbidding the delivery of damaged goods. In that law, merchandizing fraud was defined as a misdemeanor. For the initiation of a suit under this law, the statute of limitations was three years. The first complaint was registered in April 1987, but was dismissed. Finally, in March 1988, just before the statute of limitations ran out, the General Prosecutor accepted the accusation and opened an investigation.

Four doctors were tried: the director of the CNTS, his chief collaborator, the head of the transfusion laboratory, and the Director General of the Health Department. The accused stood at the center of a network with links to the ministers' cabinets, the clinicians' wards, and the hemophiliacs' families. Four stood where one hundred could have appeared, as the examining judge admitted. "It is true, we had the choice between indicting four and one hundred. But we prosecute today those who had both the knowledge and practically all the power. This has not been an arbitrary choice."[58]

In a feature that was unique to the contamination of blood drama in Europe, only doctors stood in the box. The political authorities were not whitewashed, but they were not explicitly dragged into court either.[59] As Professor Jacques Ruffié exclaimed: "I feel that medicine is being put on trial." He added: "Don't let us mix everything up. Transfusion has saved many more than it has killed."[60]

Ruffié offered the same line of argument that James Blundell, the British pioneer of blood transfusion, had offered in 1828. When attacked by colleagues on the dangers of transfusion, Blundell pleaded that medical innovations were necessarily hazardous. The romantic idea prevailed that violence was the midwife of the new world. Blundell said that if Napoleon or Timour Lenk, who were great killers, were saluted in the past as giants of mankind, why should medicine be denied the opportunity of experimenting with new therapeutic procedures? Medicine was such a benevolent enterprise, Blundell continued, that no civilization could do without it, even though it had to be admitted that it killed from time to time![61]

But Professor Ruffié made a mistake. He confused different eras. He posited himself in a time when medicine was a conjectural art and when the then current deontology was enough to protect the doctor from any exorbitant charges levelled at him by his patients. Judges have indicated their awareness of the irresistible progress of science but without untying the knot of Hippocratic obligations. At the end of the nineteenth century, physicians had

triumphantly entered the courtroom as experts,[62] foretelling a time when science would determine who was guilty and also define the extent of their guilt. Now, at the end of the twentieth century, judges were deciding on the conditions of civic science and defining what the "good practices of doctors" should have been, and what they had not been.

In 1828, the sphere of medical obligation had been defined as an "obligation of means," and not as an obligation of results. This was the lesson that medical students received during their training. This was to admit that a sphere of uncertainty enshrined their modest knowledge. The idea prevails increasingly today that patients are within their rights to demand perfectly safe procedures, from medically assisted procreation to anesthesia. In fact, the right to health, proclaimed by the World Health Organization in 1949 and incorporated in the French constitution of 1946, has opened a new Pandora's box. If science now falls in the public domain, medicine is in the process of moving from the sphere of the old guild's secrets, accessible only through initiation, towards the sphere of open knowledge, already shared by biologists, technicians, engineers, and administrative officers. New knowledge will become open to all, and will be subject to checks and updating under the eyes of the citizens. As is clear from lawyers' discourses in recent patent trials,[63] the body of generally accepted scientific knowledge has expanded, and judges now debate about science just as doctors discussed penal responsibility in the last century.

In 1764, in the years preceding the French Revolution, the physician Théophile de Bordeu commented on the decree of the upper chamber of the French Parlement on the subject of smallpox inoculation and celebrated the collaboration of justice and medicine:

> And what other aim could any doctor have today, but that of working towards the good that our august senate is preparing for society? The senate wants to hear us and to understand our dogma and our maxims. This is medicine's greatest day; *medicine will hear what justice has to say* and will lead it into the most hidden corners of the art. All our books are open; our opinions are revealed; our discussions are subject to the judgment of the wise.[64]

Bordeu comments further:

> Ten thousand subjects practice medicine in France. If our doctrine, our opinions, our morals, our expectations, and our habits were not confined within proper bounds, we would become the most fearful enemies of the people. We need liberty but we also need limits. . . . Our professional position, which seems to humble us before all men and to make us the slaves of every individual, also elevates us above all other men. Our prominence could become tyranny, as it subjects the world to our decisions daily.[65]

The trial that has ended the process of the social construction of the disease AIDS,[66] perhaps serves as a milestone from which to review the status of the medical art and the position of medicine in society, a position which had been masked by the alliance among science, medicine, and politics at the end of the nineteenth century. Law is now editing the canons of medical science: determining what is certain and what is not, what entails a responsibility and what does not.

One of the far-reaching consequences of the Contaminated Blood Affair was the effect it had on the organ transplant program.[67] Transplantation was a centerpiece of French medi-

cine, its status magnified by the work of the most recent French Nobel prize winner Jean Dausset. It embodied the unlimited ambition of scientific medicine. France-Transplant, a public interest organization that had been in charge of transplantation since the heroic days, has now been suppressed, and the state is planning a transplant agency under the strict supervision of the administration.

The Crisis of the Medical Profession

By its very success, the medicalization of society has entailed a series of changes which can be summarily characterized as "demedicalization."

The medical profession in France has undergone profound changes whose prodromata have received little attention from its members, although one indication has been the creation in 1983 of the National Committee of Ethics, initially to respond to the new challenges posed by biotechnology. The profession's mental outlook remains for the most part a nineteenth-century one. To review briefly its main elements: (1) freedom of prescription, on the part of the doctor, and freedom of choice of doctor (by the patient): the background of "liberal" medicine; (2) a Bernardian definition of medicine as an experimental science, halfway between the well-established facts of the laboratory and the obscurities of clinical medicine; and (3) an emphasis on therapeutics rather than on preventive medicine, and on the individual doctor-patient relationship.

Although current practice often contradicts this framework, the necessity for new systems of professional surveillance and political alarm has not been clearly perceived. The right to health was incorporated into the 1946 French constitution and detailed in the Social Security code. The principle was recognized that a patient was entitled to consult the doctor of his or her choice and to receive appropriate therapy whose cost would be reimbursed by Social Security. The right to health is thus clearly a model of subjective rights, "right-claims" made on society as a whole. Its sphere of application is also clearly defined.

But, in a growing number of areas of medical treatments, a prior agreement with Social Security is now required in France, which means that a government administration controls a growing percentage of medical practices. Garretta was not totally wrong when, in his defense, he claimed that he was selected for his directorship of the CNTS as a manager and not as a doctor. When lawyers reminded him of his Hippocratic oath, they pointed to the gap between individual ethics and those of the market for health. Even if the state imposes a monopolistic framework upon this market, the contradiction between the absolute value of individual health and the negotiated compromise of public health will remain.

The defects in French transfusion practices cannot necessarily be attributed to the choice of political system. Belgium and some other countries, working on principles of self-sufficiency analogous to the French ones, protected their hemophiliacs from massive contamination through the constant use of cryoprecipitates. At the other end of the spectrum, in a mercantilist system, Germany warned its hemophiliacs about the hazards of transfusion earlier than France did, and provided them with heated products, actively advertised by private companies. The defects in France may lie in the existence of a double standard which governs practices and discourses and induces perverse and painful consequences.

The "non-profit" declaration of associations such as the transfusion organization, did not mean *in strictu sensu* that there was no benefit in the business conducted, but that there was no benefit in the usual sense of the market. Therein lies the source of a misunderstanding. Director Garretta would be blamed for his financial operations, including the creation in 1990 of a holding company, "Espace vie" and various transactions with American

firms.[68] A split had occurred between the sector of unstable blood products (whole blood or red blood cells), the gifts of goodhearted people, used in cases of hemorrhagic shock and in emergencies, for which France was self-sufficient, and a much more profitable sector of manufactured blood products covering specific needs, partly derived from paid blood donations,[69] for which the demand was skyrocketing as was illustrated by the case of the hemophiliacs. Blood is not merchandise when drawn from donors, but it circulates as an ordinary form of goods[70] as soon as it is manufactured. The fact that the economy is monopolistic does not change anything about the mercantile nature of the market in which blood is placed. The not-for-profit credo should not make us ignore these basic facts. Declarations about the inviolability of the human body should not constitute screens masking reality.

As an immediate consequence of the Contaminated Blood Affair, the French 1952 law governing transfusion has already been revised as a part of a series of new general laws on bioethics, in the process of being written.[71] A January 1993 law reorganized transfusion. Only 140 centers survive. Transfusion has been placed under the strict supervision of public powers. The CNTS no longer exists. The French National Blood Agency is now permanently controlled by three experts responsible to the Health Ministry, registers all medical transactions, and supervises industrial fractionation.

The 1993 law has reemphasized the old principles of voluntary and not-for-profit donation and also that body products are not merchandise. However, in accordance with the neoliberal mood of the French government, some accommodations have been made with the practices legislated in other European countries, authorizing the free circulation in France of blood derivatives from other European countries, and even partnerships between the new "National Blood Agency" and profit-making companies. The lack of coherence that results from the gap between principles and reality risks disrupting the harmonization of European practices and, above all, creates new hazards for the future. The Committee of Ethics has reemphasized the principle of free blood donation and has suggested separating the public transfusion service and the for-profit sector, both for ethical and medical reasons, but the division seems to be difficult to implement.

In conclusion, let me emphasize the originality of the French case. First, the French Contaminated Blood Affair had two characteristics: (1) the French government took the initiative in handling the compensation payments, whereas in other countries matters were settled through insurance companies; and (2) individual French citizens initiated a broad range of lawsuits in a variety of courts ranging from administrative tribunals to the European Court of Justice. The doctors had to account for actions for which they were previously not considered legally culpable. Second, there were two philosophies about how to proceed: (1) pay compensation for the contamination of blood in the name of national solidarity without seeking to assign guilt and remain openminded with respect to the evidence and the dates involved, according to the doctrine of therapeutic risk; and (2) pay compensation as a result of legal action proving guilt. This would presuppose that experts could determine precisely the relevant standards of scientific knowledge in this field.

These choices continue to be publicly debated. The *Conseil National du SIDA* (National AIDS Committee) has discussed the fact that those at risk from contamination receive compensation apart from that received for general therapeutic risk and that this measure will reinforce the division between "innocent" and less innocent victims.

We are watching a final episode in the decline of the autonomy of the medical corporation. The creation of the French National Committee of Ethics has already made it clear that a number of decisions no longer belong to the medical profession[72] but to the nation, and that the position of doctors should diminish to one that is more fully integrated into

society. Social solidarity has been an argument for those advocating universal compulsory testing for AIDS as a requisite for "disclosure," the English word for the French "transparence,"[73] and as a measure that avoids discrimination against high risk groups.[74] The trial, as painful and as dramatic as it has been, perhaps marks a decisive turning point in the evolution of French democracy, and may initiate a healthy review procedure of its principles in the medical domain. It cast some light on alarm mechanisms that did not function during the Contaminated Blood Affair and could suggest new means to preserve and to implement the right to health, a legal conquest of the twentieth century. It is to be hoped that the trial has opened a salutary crisis in the Hippocratic sense.

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Notes

1. A selection of the daily trial chronicles has been published by the newspapers *Le Monde*: Laurent Greilsamer, *Le Procès du sang contaminé* (Paris: *Le Monde* éd., 1992) and *Libération*: special issue *Le Sang Contaminé*, May 1993. These will be referred to in the end notes respectively as Greilsamer and *Libération*.
2. The *Ordre national des médecins*.
3. Zaki Laïdi, *L'Ordre relâché: Sens et puissance après la guerre froide* (Paris: Presses de la Fondation nationale des sciences politiques de Paris, 1993).
4. Marie-Angèle Hermitte, "Le droit dans le drame de la transfusion sanguine," *Autrement*, January 1994: 200–226.
5. J.-J. Lefrère, A.-M. Courroucé, J.-Y. Muller, *Transfusion sanguine et SIDA* (Paris: Frison-Roche, 1991).
6. The Director General of Health is analogous to the American Surgeon General.
7. Agnès Parturier, *L'Oeuvre de la transfusion sanguine d'urgence*, medical thesis, Paris, 1933.
8. Jean-Pierre Baud, *L'Affaire de la main coupée: histoire juridique du corps* (Paris: Seuil, 1992), 194.
9. "Et cette effusion de sang (du Christ et des martyrs) est un trésor déposé dans le coffre de l'Eglise, dont l'Eglise a la clef." Petrus Albinianus Tretii, *Tractatus aureus de pontificia potestate*, quoted by Baud, *L'Affaire*, 150.
10. B. Fantus, "Blood preservation," *JAMA* 109(1937): 129.
11. For a comparative analysis of Tzanck's *Oeuvre* and Fantus's *Bank*, see Anne Marie Moulin, *Le Dernier Langage de la médecine: histoire de l'immunologie de Pasteur au SIDA* (Paris: Presses universitaires de France, 1992), 160-163.
12. This is why the lawyers in the 1992 lawsuit referred to the 1905 law on manufactured goods aimed at the general consumer, and not to the post-war legislation on pharmaceutical products. Manufactured

blood products have been assimilated into industrial goods, and are accountable to contractual obligations. Sabine Paugam, the lawyer who pleaded the charge of homicide by poisoning, a charge that was not accepted by the court, commented ironically on a law in which blood was placed side by side with mustard and pots of yogurt. Greilsamer, 93. See also Sabine Paugam, *Un Sang Impur* (Paris: Lattès, 1992).

On the legal status of remedies and drugs in France, see Anne Marie Moulin and A. Guenel," L'Institut Pasteur et la naissance de l'industrie de la santé," in Jean-Claude Beaune, ed., *La Philosophie du remède* (Paris: Champvallon, 1993), 91-109; see also in the same book, J. Azéma, "La définition juridique du médicament," 37-39; Olivier Faure, "Le succès du médicament en France au 19e siècle et ses significations," 216-225. In the struggle against secret remedies (see Matthew Ramsey, *Professional and Popular Medicine in France, 1770-1830: The Social World of Medical Practice* [Cambridge: Cambridge University Press, 1988)], in France, the law has been slow in establishing the status of medicines.

13. Michel Foucault, *La Naissance de la clinique* (Paris: Presses universitaires de France, 1963).
14. L. and H. Hirszfeld, "Serological diifferences between the blood of dfferent races," *Lancet* 180(1919): 676-678.
15. Moulin, *Le Dernier Langage*, 163-177; on blood groups and human anthropology, see William Schneider, *Quantity and Quality: The Quest for Regeneration in Twentieth-Century France* (Cambridge: Cambridge University Press, 1991), 218 and following, and his "Chance and social setting in the application of the discovery of blood groups," *Journal of the History of Medicine* 57(1980): 545-562.
16. French National Committee of Ethics, *Transfusion sanguine et non-commercialisation du corps humain*, 1992, 23.
17. The volunteer donor-based system admitted exceptions. Businessman Mérieux retained a privileged position because he had supplied the *maquis* (French partisans) with blood during the war. He was authorized to manufacture gamma globulin from hyperimmunized donors until Minister Veil withdrew this permission in 1977. See *Le donneur de sang* 137(1974): 15-20; "Le prix du sang," *Valeurs actuelles*, 16 February 1976.
18. His general thesis is that designating blood as a product would have submitted transfusion to direct control by the state and guaranteed against falsification.
19. Dominique Thouvenin, "Les projets de loi sur le corps humain: des principes généraux pour une législation spéciale," *Prévenir* 22(1992): 74-96.
20. See the cartoon *SIDA Connection* which popularized the issue (Paris: Bagheera, 1991).
21. Marie-Angèle Hermitte's manuscript on the history of transfusion, to be published by La Découverte, with the author's gracious permission.
22. Bernard Kouchner, Health Minister: "We shall always be lagging behind for the latest virus, but at least let us lag as little as possible. (Nous serons toujours en retard d'un virus. Mais au moins, que l'on soit le moins en retard possible.)" *Libération*, 27 May 1992, 61.
23. In 1984, the entrepreneurial Garretta succeeded hematologist Soulier. Garretta remained in this position until 1991.
24. To cite just one example, in 1945, mistakes in blood grouping were not unusual. In a provincial city, witnesses recall the case of a donor, whose health status was poor (he was an alcoholic) but who was so easy-going (he was a doorkeeper next to a maternity ward), who repeatedly provoked reactions in recipients before it was found out that his blood was not too "strong" as the donor claimed, but patently incompatible.
25. *Sciences de la vie: De l'éthique au droit*, Etude du Conseil d'Etat (Paris: La documentation française, 1988), 35.
26. Jean-Pierre Soulier, "En attendant qu'un test biologique spécifique soit découvert, on peut donc penser qu'en France, où le don du sang est strictement bénévole, le risque transfusionnel du SIDA est extrêmement faible." Soulier, *Le Sang: Introduction à l'hématologie et à la transfusion* (Paris: Flammarion, 1983), 217; to be compared with his *Transfusion et Sida: le droit à la vérité* (Paris: Frison-Roche, 1992).
27. Richard Tittmuss, *The Gift Relationship* (New York: Pantheon Books: 1971).
28. Anne Marie Moulin, "Body parts: the modern dilemma," *Transplantation Reviews* 25(1993): 33-35; Club de la Transplantation, *Droit à la santé et à la transplantation: La compatibilité culturelle* (Paris: Cilag, 1994), 16–30.
29. A. W. Drake, S. N. Finkelstein and H. M. Sapolsky, *The American Blood Supply* (Cambridge, Massachusetts: MIT Press, 1982).
30. Y. Sultan, 4 June 1983, "On soigne les malades, on prévient les maladies, c'est la marche irréversible. Il

ne faut pas marcher dans le sens inverse de l'histoire. Nous avons enclenché le problème de la prophylaxie des hémophiles, je crois que le plus raisonnable c'est de marcher dans ce sens." Soulier, *Transfusion et SIDA*, 187 (Appendix 7-2).

31. For the real figures on imports, see Soulier, *Transfusion et SIDA*, 207-210 (Appendices).
32. Claude Got, *Rapport sur le SIDA* (Paris: Flammarion, 1988). At the DGS, only one epidemiologist was in charge of the AIDS file until 1985.
33. Bernard Seytre, *SIDA: Les secrets d'une polémique; recherche, intérêts financiers et médias* (Paris: Presses universitaires de France, 1993), 35-50.
34. Willy Rozenbaum, Didier Seux, and Annie Kouchnner, *SIDA: réalités et fantasmes* (Paris: P.O.L, 1984).
35. See the paternalistic way Soulier evokes Jean Péron Garvanoff, the leader of activist hemophiliacs, "Je n'ai pas oublié l'enfant sensible et attachant qu'était le petit Jean Péron Garvanoff, aujourd'hui si acharné contre le CNTS," Soulier, *Transfusion et SIDA*, 6.
36. Marie-France Couilliot and Anne Marie Moulin, "La pathogénicité des Crypotosporidia chez l'homme," paper given to the French Society of Parasitology, Paris, 17 December 1982.
37. Atlanta, April 1983.
38. Seytre, *SIDA: Les secrets d'une polémique*, 171-193.
39. This euphemism was attributed to the impossibility of forbidding the sale of something which was not subject to the regulations on medicines.
40. A few transfusion centers settled on a rigorous mode of exclusion from the very beginning.
41. I follow Michel Setbon's analysis on this point in his chapter, "La transfusion sanguine sous la menace du SIDA," *Pouvoirs contre SIDA: De la transfusion sanguine au dépistage: décisions et pratiques en France, Grande Bretagne et Suède* (Paris: Seuil, 1993), 172-221.
42. *Libération*, 2 November 1992, 61.
43. As they did in Sweden, for example. See Setbon, *Pouvoirs contre SIDA*, 293 and following.
44. Seytre, *SIDA: Les secrets d'une polémique*, 144 and following.
45. The results were published by the *Quotidien du Médecin*, a widely read medical journal aimed at the general practitioner, in March 1985. Soulier, *Transfusion et SIDA*, 121.
46. "*Une période intermédiaire* (emphasis mine) de quelques semaines où ces produits coexisteront avec des produits non chauffés et non encore utilisés, *est acceptable*. Dès maintenant, des fractions chauffées ou d'importation doivent impérativement être distribuées aux hémophiles LAV négatifs." Meeting of the National Committee of Hemophilia, 19 June 1985.
47. Samples which had been returned in September were recycled among the "naive" hemophiliacs as was revealed during the trial. Greilsamer, 121. Sporadic contamination went on at least until 1 October 1985 when unheated products were no longer reimbursed by the Social Security.
48. Arnault Tzanck and P. Chiche, *Réanimation et transfusion sanguine* (Paris: Doin, 1945), 158. Chapter on the transmission of infectious diseases through transfusion: "Nous ne faisons que mentionner ce cadre d'accidents qui sont évitables par une étude soigneuse du donneur et par une bonne technique de laboratoire. . . . Ces notions ne doivent pas . . . dispenser d'un examen sérologique du donneur dont le manque risque d'avoir, au point de vue médico-légal, des effets désastreux."
49. Seytre, *SIDA: Les secrets d'une polémique*, 171-193.
50. Soulier admits that weeks were lost between June and August, but pleads that it was necessary, before making the test compulsory, to compare the three candidate kits, *Transfusion et SIDA*, 117. During the same period, the FDA withheld approval of the Pasteur Institute test.
51. J.-P. Allain, *Le SIDA des hémophiles: Entretien avec Fabienne Prat* (Paris: Frison-Roche, 1993).
52. A theme mentioned in June Kramer, "Letter from Europe: Bad Blood," *The New Yorker*, 11 October 1993, 74-95.
53. Auzias-Turenne, *La Syphilisation* (Paris: Poulain d'Andecy, 1878).
54. Jean-François Picard and Martine Bungener, "Quelles recherches pour le SIDA?" Report for INSERM, CERMES, December 1991.
55. Got, *Rapport sur le SIDA*, 71.
56. Along with the *Agence française de lutte pour le SIDA* (AFLS), et le *Conseil du SIDA*, concerned with the ethical and moral aspects of the epidemic.
57. The first book that covered the main events was written by Anne Marie Casteret. She informed the general public for the first time about the Affair in *L'Evènement du Jeudi*. See Anne Marie Casteret, *L'Affaire du sang* (Paris: La Découverte, 1991).

58. "C'est vrai qu'il y avait le choix entre quatre et cent inculpés. Mais nous poursuivons aujourd'hui ceux qui savaient et qui pouvaient pratiquement tout. Ce n'était pas un choix arbitraire." Greilsamer, 3 August 1992, 187.
59. As former Prime Minister Rocard remarked: "N'être jamais jugé, c'est n'être jamais acquitté." *Libération*, 64. In France, ministers are accountable only to the Haute Cour de Justice, a very special court, which, if it convenes, breaks parliamentary immunity.
60. "J'ai l'impression qu'on fait le procès de la médecine. Il ne faut pas tout mélanger dans la vie. La transfusion a sauvé beaucoup plus de personnes qu'elle n'en a tué." Greilsamer, 134.
61. James Blundell, *The Principles and Practice of Obstetrics* (Washington, D.C.: Duff Green, 1834), 427.
62. Pierre Darmon, *Médecins et assassins à la belle époque: La médicalisation du crime* (Paris: Plon, 1989).
63. Alberto Cambrosio, P. Keating, and Michaël Mackenzie, "Scientific practice in the courtroom: the construction of sociotechnical identities in a biotechnology patent dispute," *Social Problems* 37(1990): 301-319.
64. "Et quel autre objet peut avoir aujourd'hui tout médecin que celui de concourir au bien que notre auguste sénat prépare à la société? Il veut nous entendre et pénétrer dans nos dogmes et nos maximes. C'est le plus beau jour de la médecine, elle écoutera la justice et la conduira dans les détours les plus cachés de l'art. Tous nos livres sont ouverts, nos opinions particulières sont dévoilées; nos discussions sont soumises au jugement des sages." Théophile de Bordeu, *Recherche sur quelques points d'histoire de la médecine* (Paris: Caillau, 1764), 8-9.
65. Idem, 10. "Dix mille sujets exercent la médecine (in France). Si notre doctrine, nos opinions, nos moeurs, nos prétentions, nos usages, n'étaient contenus dans de justes bornes, nous pourrions devenir les ennemis les plus à craindre des peuples, il nous faut de la liberté mais nous avons besoin de frein . . . . Notre état qui semble nous humilier devant tous les hommes et qui nous rend les esclaves de chaque particulier, nous élève au-dessus de tous; notre élévation pourrait se changer en tyrannie, puisqu'elle soumet le monde à nos décisions journalières."
66. Claudine Herzlich et Janine Pierret, "Une maladie dans l'espace public: le SIDA dans six quotidiens français," *Annales E.S.C.* 5(1988): 1109-1134.
67. Anne Marie Moulin, "AIDS and the right to health," in *AIDS, Health and Human Rights* (Les Pensières: Fondation Mérieux, 1993), 67-73.
68. *Libération*, 63.
69. Through the importation of blood products derived from paid collection in the United States or other countries such as Latin America (Brazil...). See Piot Hagen, *Blood: Gift or Merchandise* (New York: Alan Liss, 1982); Gerd Fätkenheuer, *Marchands de Sang* (Paris: Cetim Favre, 1986).
70. Since 1990, the fiscal system imposes a "value added tax," which confirms the nature of blood at this point (a suggestion from Dominique Thouvenin).
71. "Projet de loi relatif au corps humain et modifiant le code civil," *Prévenir* 22(1992): 97 and following.
72. Anne Marie Moulin, "Medical ethics in France," *Theoretical Medicine* 9(1989): 271-285.
73. François Dagognet, for example, suggests emphasizing the obligation of fulfilling moral duties, in *Corps réfléchis* (Paris: Odile Jacob, 1990), 84-85. So does Jean-Pierre Peter, "Dimensions mythiques des épidémies et SIDA," *Action et recherches sociales* 3(1989): 15-29. Georgina Dufoix, former Minister of Social Affairs and Health during the crucial months of 1985, in a plaidoyer *pro domo*, also takes this tack: "Is it fair to raise the issue of compulsory testing in terms of individual freedom?" Open letter to the public, 5 October 1992.
74. After some heated debate, mandatory testing has been dropped as an inefficient measure (the rate of positivity in non-voluntary testing is very low) and finally as counter-productive: the false certitude of a negative test can induce risky behavior. See Setbon, *Pouvoirs contre SIDA*, 195-207.

Women's Destiny and AIDS in Uganda

Maryinez Lyons

> When you educate a man, you educate an individual but when you educate a woman, you educate a nation.[1]

The World Health Organization has predicted that the "social vulnerability" of most African women places them in grave danger of AIDS. Early in 1991 the United Nations Development Programme (UNDP) warned Ugandan officials that unless there was effective intervention quickly, the consequences of the high rate of HIV among women in Uganda "would be disastrous."[2] More than sixty million dollars was released for development of Uganda over four years and UNDP decided to "allocate a big chunk of the money to raise the standards of women." It is not clear what the UNDP means by raising the standards of women. Before women can have more access to education or to means of earning a living, both of which will result in improved health, it will be necessary to effect major changes in powerful cultural attitudes and practices. Raising the standards of women in Africa would be a truly "effective intervention" in the AIDS epidemic. There have been many attempts in the past to improve the lot of Ugandan women, yet today the vast majority live much as their mothers and grandmothers did before them, working long hours digging, carrying, and caring for their families with only the assistance of primitive technology. Clearly there has been strong resistance to changing women's status.

On World AIDS Day in 1990, the president of Uganda acknowledged the importance of women as "the actual moulders of people" and he called for "women to take destiny in their hands and resist exploitation"[3] (see Figure 1). While this is splendid advice for African women, it is not easily taken by those in Uganda whose entrenched roles of "dependency, submission and passivity" not only relegate them to the status of "second class citizens," but also make them particularly susceptible to HIV infection.[4]

"Epidemics have been as profound an agent for societal change as wars. Unless brought under control, AIDS will undermine decades of progress towards improved health and a sustaining economy."[5] These phrases from a Ugandan newspaper have particular meaning in a country only recently emerging from decades of appalling disruption. During the past twenty-five years Uganda came to

> symbolize Third World disaster in its direst form. Famine; tyranny; widespread infringements of human rights, amounting at times to genocide . . . malaria; cholera, typhoid, and a massive breakdown of government medical services; corruption, black marketeering, economic collapse; tribalism, civil war, state collapse—think of any one current Third World affliction, and most probably Uganda will have suffered it . . .[6]

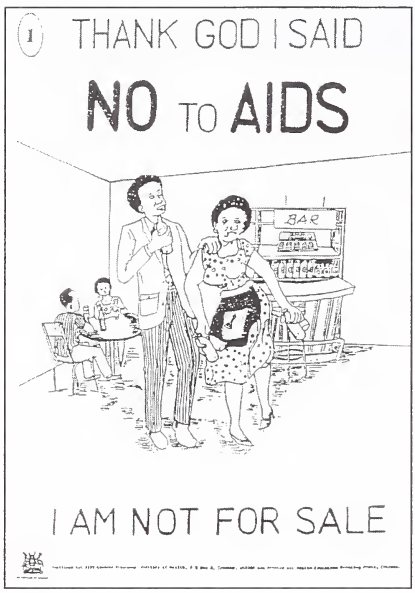


Figure 1.
Source: Uganda AIDS Control Programme

It is almost too much to add AIDS to this depressing list. Everyone is affected by AIDS in Uganda at the very time when contributions to the process of national reconstruction are critical. But the impact of AIDS on women will have especially serious consequences for the future of the nation. Women underpin much of the agriculturally based economy, in addition to their role as primary carers of the young and ill. All Ugandans will suffer the consequences of female morbidity and mortality. AIDS is clearly a heterosexual disease in Uganda, as it is elsewhere in sub-Saharan Africa, and attention is turning to ways of empowering women so that they can avoid infection. Enabling African women to control their own bodies and lives is a complex political, social, and economic issue. There are important precedents for many of the current attitudes concerning the place of African women in society and their role in relation to sexual disease. Deeply embedded in culture, such attitudes are resistant to change and will present enormous difficulties for successful interventions.

Much more remains to be said about the plight of women in Uganda, but first a brief look at the Ugandan AIDS epidemic.

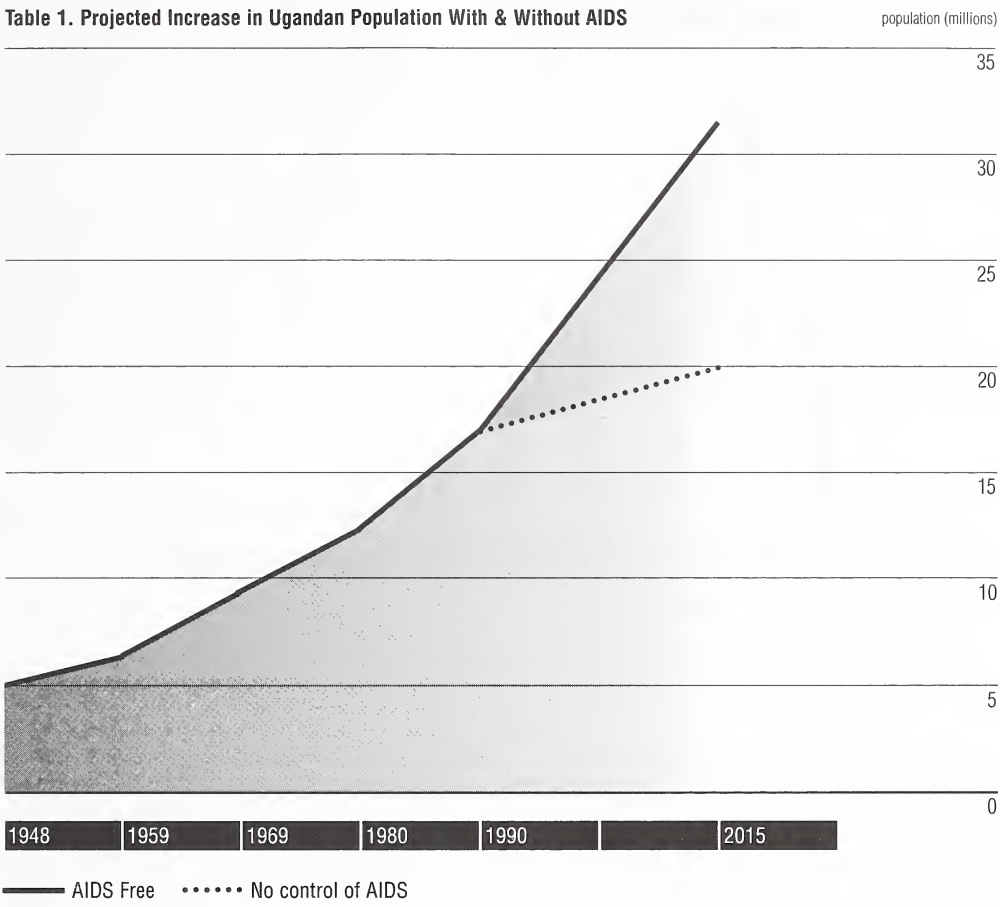
Scale of the Epidemic

Nearly every Ugandan has been either afflicted or affected by AIDS.[7] AIDS was first officially recognized in the country in 1982, and by 1992 the AIDS epidemic in Uganda had reached a scale equalled in few other African nations. Current estimates of HIV infection rates range from 30 percent to 40 percent among young, urban adults, while rural rates tend to vary from 6 percent to 12 percent. It is estimated that over one and a half million Ugandans, in a population of some sixteen million, now carry the virus. Hospitals that were already unable to cope before the AIDS epidemic have been burdened by the increase in numbers of patients. In urban hospitals like those at Mulago, Rubaga, and Nsambya, about 40 percent of beds are occupied by patients with AIDS-related illnesses.[8]

Demographic Impact

Yoweri Museveni, the president of Uganda, noted for being the first African leader to acknowledge the epidemic, opened the 1991 International AIDS Conference with a moving speech. He referred to a mathematical model developed by the United States-based Futures Group which projected an alarming potential demographic impact of AIDS in Uganda (see Table 1). By 2010, without successful intervention, Uganda could lose 12 million people to HIV/AIDS. In other words, the population would number 20 million instead of the projected 32 million.[9] Of the two million orphans already existing in Uganda, it is believed that

Table 1. Projected Increase in Ugandan Population With & Without AIDS



Source: Futures Group, 1991

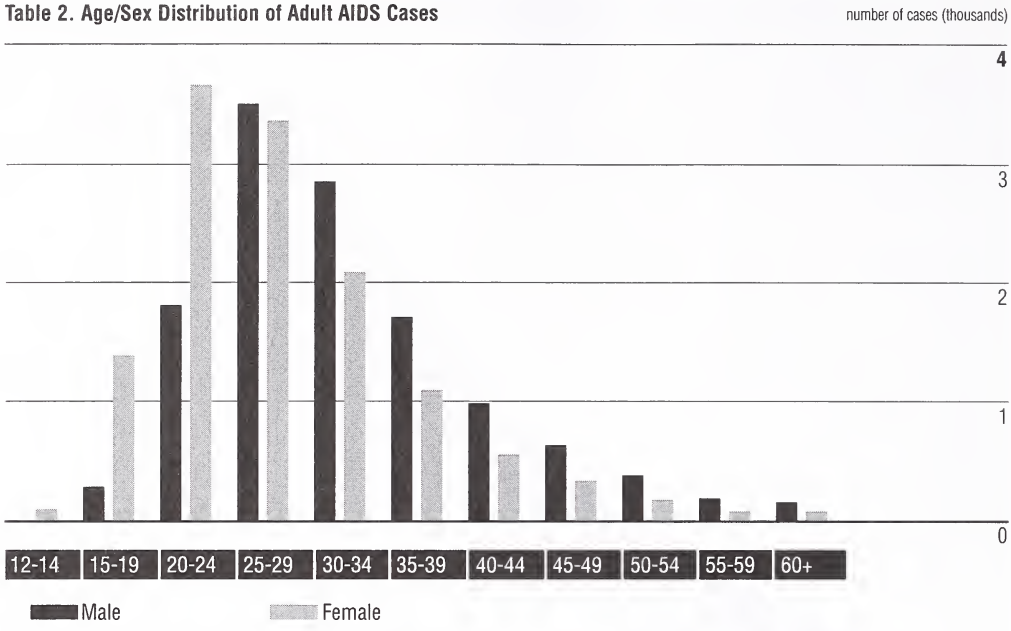
1.5 million have resulted from AIDS deaths. But worse still, Museveni has been warned to expect some five to six million orphans by 2010.[10] The president is convinced that AIDS is no longer merely a health problem. As it will affect all areas of social and economic life, a new approach to the epidemic is required. In 1991, the government decided to adopt a multisectoral approach to the epidemic and established the AIDS Commission, an independent body under direct supervision of the president.[11]

The present population of Uganda is 16,583,000.[12] Fifty percent of the population is, in demographic terms, dependent, that is *below* the age of fifteen. Most of this age group is free of HIV.[13] The dependency ratio of a population is an important measure when predicting the impact of AIDS which affects the very age group supporting dependents. In Uganda there is only one working age adult for each child, whereas in most developed countries the ratio is more likely to be two or three adults per child[14] (see Table 1).

By August 1991, 83 percent of the reported[15] 24,977 AIDS cases were young adults between the ages of 15 and 40[16] and the sex ratio was 1:1[17] (see Table 2). It is clear that AIDS in Uganda affects nearly equal numbers of women and men aged 15 to 40.[18]

About 40 percent of the total population is aged 15 to 40 and if it is recalled that over

Table 2. Age/Sex Distribution of Adult AIDS Cases



Source: Uganda AIDS Control Programme, December 1991

1.5 million Ugandans are probably infected, it is likely that nearly one quarter of all young, sexually-active people aged 15 to 40 in Uganda is HIV positive. This age group is the major contributor to both production and reproduction and if present projections of HIV morbidity and mortality are correct, the loss of a significant proportion of young adults will have a disastrous impact on the reconstruction process.

HIV rates at antenatal clinics are used by epidemiologists to calculate the possible future impact of AIDS. Women of childbearing age constitute 22 percent of the total population and in many regions it is these women, aged 15 to 30, who have the highest levels of HIV infection.[19] It is now accepted that the presence of another sexually transmitted disease, particularly one involving genital lesions, enhances transmission of HIV. Rates of syphilis among antenatal women are alarming.

AIDS Related Mortality

A long-term project researching the population dynamics of HIV-1 transmission began in 1989 in a rural sub-county of Masaka District, in south-west Uganda, believed to be one of the worst affected regions in the country.[20] The baseline study established an overall seroprevalence rate of 8.2 percent for adults (aged 13 years or more), and two years later the director of the project reported a dramatic mortality rate. By 1992, 23 percent of the HIV-positive adults had died. This disturbing rate of disease progression is about twice the rate observed in industrialized countries. Dr. Daan Mulder, the epidemiologist in charge of the program, explained that in the area of the study "Young adults infected with HIV-1 have a risk of dying which is sixty times the risk of the non-infected. More than 50 per cent of all adult deaths and more than 80 per cent of deaths in young adults are HIV-1 associated."[21]

Unquestionably, all areas of life in Uganda will be affected by an epidemic disease with such high mortality. Individuals, families, communities and the nation will be diminished. It might be asked how Ugandans will cope with this disaster, especially in light of the already overstretched medical services.

Economy of Health/Medical Services

In 1991, with a per capita Gross National Product of U.S.$170 and life expectancies of 46 years for males and 47 years for females, Uganda was listed by the World Bank among low-income national economies.[22] Defense absorbs 15 percent of the national budget whereas between 1986 and 1991 health was allocated an average of 4 percent.[23] By 1987, donor agencies accounted for 61 percent of *all* funds for government health services in Uganda.[24] To put these figures into a regional context, compare them to those of neighboring Kenya where defense received 9 percent and health 7 percent.[25]

From the mid-1930s until 1970 the government allocated a minimum of 6.5 percent of total recurrent and capital budget to health services and by 1971, "Uganda had a level of health services far better than many developing countries."[26] During the Amin government from 1971 until 1979 the situation changed dramatically. With the expulsion of some 80,000 Asians in 1972, followed in 1973 by the sudden departure of half of the some 1000 doctors in the country, the health services deteriorated quickly. By 1985 health care delivery was roughly half, in terms of money spent, the early 1960s level. Real purchasing power of the health budget dwindled to 6 percent of the 1968-69 level. Of course, it was not only the health sector which disintegrated. During the decade between 1972 and 1982 per capita income dropped 25 percent while consumer prices increased 1200 percent.[27]

Other revealing statistics for 1987 were a crude birth rate of 50, a crude death rate of 17, and an infant mortality rate[28] of 101. By 1992, Uganda had one doctor per 25,000 people compared to about one per 1000 in the United Kingdom and 2 per 1000 in the United States.[29] In Uganda, annual expenditure for *all* health care in 1990 was U.S.$6 per capita and one HIV test cost between U.S.$3.50 and U.S.$5.00. The Ministry of Health estimated the cost of care for one AIDS patient at between U.S.$500 and U.S.$1000.[30]

Women in Crisis

To return to women, the focus of this essay. As in all crises on such a scale, the epidemic of AIDS has exacerbated many existing social problems. Tensions and inequalities between men and women are clearly revealed as AIDS inexorably undermines social and economic structures. Ugandan women are particularly vulnerable to any new pressures. Disturbingly, women are often blamed for spreading the virus. Women not in socially sanctioned relationships with men are targeted for much blame and harassment. In some areas single women, or women on their own, have been chased away from their homes. Those few women who manage to survive through entrepreneurial skills and establish small businesses are often accused of spreading AIDS. It is no surprise that women who manage to achieve a modicum of independence in Uganda are fiercely resented. Even children point the accusing finger at women. In a recent survey of school children, 83 percent "believed that AIDS is transmitted only by women."[31] A senior official in the Ministry of Education believes that some of the AIDS Control Programme messages, such as "Love carefully" and "Zero grazing," have contributed to this bias as they were understood to be aimed at men.

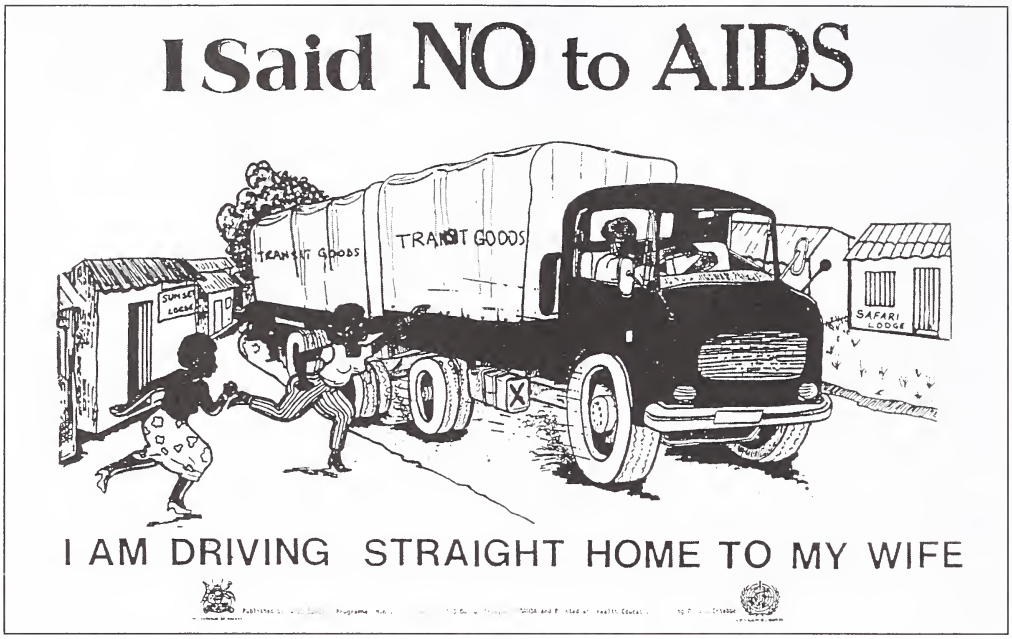


Figure 2.

Source: Uganda AIDS Control Programme

And equally disturbing is the widespread belief that women infected with HIV go about the country maliciously infecting others.[32] A poster designed by a male for the AIDS Control Programme illustrates this bias. Two prostitutes are depicted aggressively accosting a male lorry driver (see Figure 2).

While attention is beginning to turn to the potential impact of AIDS on the national economy in Uganda, there has been more limited awareness of the economic implications of women and AIDS. The secondary role of women in many African societies has been examined and lamented, but Ugandan women are especially disadvantaged in the context of subsaharan Africa.[33] As one researcher found in Uganda, "To be masculine means to provide for and control women. To be feminine is to be pleasing and acceptable to men."[34] This ideology reflects the economic reality that men have access to the wider cash economy while women are bound to the village and the subsistence agricultural economy they sustain.

The Social Vulnerability of Women

The majority of Ugandan women live in relation to men as clients. There are many proverbs, jokes, and myths concerning woman as the "weaker vessel," for example, "Two equal pieces of wood do not start a fire," and "The pride of a proper woman is a husband."[35] Marriage is crucial to women's survival. The vast majority of women are married by the age of twenty with significant percentages married by sixteen. There are several types of union recognized as "marriage"; these include civil, religious, and customary unions. Most Ugandans live together under customary law which means that most women fall outside the protection of the legal system.

The social vulnerability of Ugandan women which makes them more susceptible to HIV

infection needs to be examined more closely. In most Ugandan tribes, daughters are less valued than sons by their fathers.[36] Fathers appreciate daughters primarily for their exchange value in the form of bridewealth at marriage.[37] Bridewealth consists of goods and cash paid by the husband's male kin to the father of a daughter to recompense his loss of her reproductive and productive value to another man. In southwest Uganda large numbers of young men, unable to afford bridewealth, remain unmarried until their thirties. Bridewealth in effect establishes a "contract" between two family groups for "marriage is a communal affair and [there is] nothing individual about it."[38] Among the Acholi, a woman is known as *dako*, "one who transfers," a definition which covers most women in the country. Women are transferable assets.

Women have less access to education because many families are unwilling to invest in a daughter's education in spite of the fact that an educated woman commands higher bridewealth.[39] In my own survey carried out for the World Health Organization in 1992, I found 85 percent of rural women in Kabale District and 66 percent of urban women in Kampala had no, or only some, primary level education in contrast to 74 percent of rural men and 41 percent of urban men. The lower educational levels of most women mean fewer options for survival on their own, the situation of increasing numbers of women in Uganda. Women who outlive partners dying prematurely have a very limited range of survival strategies.

The most obvious survival strategy, that of remaining on the property formerly shared with deceased partners and continuance of cultivation in order to feed selves and children, is not available to many women because the vast majority of Ugandan women cannot inherit land or property.[40]

Women acquire access to land on which to cultivate crops to sustain their own and their children's lives through the patronage of a father, brother, or partner. A Ugandan female judge puts it bluntly, "In most tribes of Uganda, under Customary Law, the wife is seen as an outsider or stranger. She is not allowed to inherit land. That is why in some tribes a widow is inherited [by brothers-in-law] or she must return to her parents."[41] Most women can remain with their children only while in a relationship with the biological father. Children produced by the woman belong to the male partner and his male kin and should he die, his male kin acquire both the children and property. If the woman is fortunate, she will be tolerated, perhaps allowed to continue residing in the home and cultivating her patch of land. However, many woman are forced to fend for themselves, an increasing tendency as AIDS-related deaths increase. Judge Kikonyogo tells us that "relatives . . . often . . . forcibly evict the widow, especially if she had no children or had daughters only. Women are assaulted, intimidated, framed up with all sorts of allegations, and even murdered."[42] The press is filled with poignant reports of dispossessed women.

This is not a recent practice. Thirty years ago, a newspaper reported that "In many parts of Uganda it still happens that when a man dies his widow is left destitute. His heir and relatives come and take all the property, even the widow's cooking pots, chickens, tables and chairs."[43]

Patrilineal Kinship Systems and Fragile Social Networks

Evidence of the increasing vulnerability of women due to AIDS comes from the Ugandan Association of Women Lawyers. They report that the majority of their cases now involve AIDS and women's rights to children, land, and property. The AIDS epidemic is raising new questions about women's roles within the family and rights before the law. One of my

informants illustrated this dilemma well. A very elderly, illiterate, and impoverished grandmother in rural Kabale described how her son and his two wives had died of AIDS. She was left with ten grandchildren aged two to fourteen. I had arrived early to interview Peria[44] whom I found, barefooted and in rags, "digging" with an iron hoe weighing fifteen pounds. When I asked if she was helped by relatives, she angrily retorted, "I don't get any help from relatives at all for cultivation. My two sons want to grab my property. So how do you think other people can help me when my sons are showing a bad example."[45] Peria's two remaining sons were trying to "grab" their dead brother's land and two cows. It was rumored that the two sons sent their *emandwas* (spirits) to kill her and the children.[46] Peria's case is typical in Uganda today.

In general, widows are impoverished, but the widows of those who have died of AIDS are especially so. In addition to finding means of survival for themselves and children, they may have to pay off debts incurred during the prolonged nursing of their husbands.[47] The pioneering AIDS Support Organization, TASO, is particularly concerned about the fate of AIDS widows who more than other women have extremely few options for survival. Many assume "When women separate or become widows they can survive by selling sex."[48] This was the view of many women I interviewed, disturbing evidence that women, as well as men, cannot easily sanction independence of members of their own sex.

Separation, Divorce, and Spinsterhood

Separation and divorce are extremely difficult situations for Ugandan women as any form of spinsterhood is socially disapproved. In the past spinsters were suspected of having diseases such as tuberculosis or leprosy.[49] Today AIDS is included. "African society has no defined role for a spinster, and she is unwelcome even when she divorces and returns home."[50] This attitude is in part caused by economic necessity—a divorced woman's family is obliged by custom to return the bridewealth paid by the husband's family. But bridewealth is often reinvested or spent on the marriages of sons. "Divorce is not common because of the bridewealth. Once it's paid, you have got to suffer and face the problems. You are not welcome back home [father's household] . . . and even your brothers won't accept you."[51]

Widows resulting from AIDS deaths of their husbands are in a doubly difficult situation. Not only are they viewed by the own kin as an unwelcome economic burden, they are often regarded as potentially polluting by kin and neighbours alike. Many "AIDS widows" attempt to escape this double stigma by moving to new areas in spite of their limited choices for survival, and there are numerous reports of women newly-arrived in areas being victimized.

Sexual Partners and AIDS

Women have very little power to negotiate sexual relations. In the course of my research in Uganda over the past three years, many women candidly expressed their fears concerning catching AIDS from their partners. The women revealed deeply stoical attitudes about their relationships, which they very much feared would lead to their own deaths but which they felt unable to escape.

> How can we avoid AIDS?. . . I have a husband and I do not know his movements so I cannot be sure. I can give lip service and say I fear the dis-

> ease but I still live with my husband so I cannot be sure . . . [because he] has other partners outside our marriage.[52]

Thirty-three percent of women are in polygamous unions, which complicates the control of sexual disease, and many women voice anxiety about their co-wives, "My husband has two other wives. . . . This worries me a lot for I cannot trust these women not to have other partners."[53] Where could this young wife go if she left the husband who gives her access to land on which to grow food and a house to stay in with her children?

A nurse at a small, rural dispensary hoped to educate her clients about the hazards of AIDS. She said that all her female patients complained of husbands who would not take AIDS seriously. The same nurse confessed her own deep anxiety:

> Even I think I am going to die because my man is not stable. We are all going to die. I hear people saying he is with that one and . . . I don't know how I could live away from him because we have small children and I am pregnant now. We cannot talk about his other women . . . he will stop me and shout me down . . . I don't know . . . I shall just die . . . there I become stuck and have nothing to say.

She explained why many women feel compelled to remain with men even when convinced it means death:

> It's those small children. . . . The main problem [in leaving] is that you cannot leave the children behind . . . you die with them. If you suggest divorcing them [men who run around] the whole of Uganda will not be married![54]

Another woman in the badly affected Masaka district said that she thought a lot about AIDS and worried about her sick co-wife whom she described as "adulterous." She lamented that whenever she tried to discuss this anxiety with her husband of eleven years he would tell her to go back to her parents, a most unrealistic option.[55]

Kyeyombekire—"She Builds for Herself"

Women who manage a degree of independence through their own entrepreneurial skills often find themselves the target of envy, hostility, and even blame for spreading AIDS. Women, as well as men, view independent women as dangerous. A female informant expressed typical ambivalence towards independent women. She described her own sister whose husband had divorced her because of his strong objection to her owning vehicles and land. My informant continued, "In Buganda, women can build!" but immediately added the comment, "But such women are not respected. They are *malaya*[56] (prostitutes)."[57] Another female informant elaborated reasons why independent women are dangerous: (1) they control their own sexuality which can be offered to men at will; (2) they might be *forced* by economic circumstances to use sex as a survival strategy; and (3) women on their own are assumed to be HIV positive. After all, goes popular thought, in what other way could a Ugandan woman survive on her own?

> The men are attracted by those very women who support themselves and have no husbands. Some women who support themselves are dangerous because after digging they go to the bars and meet men. Very few married women run around. How can you be attracted by a sick woman and every woman who is alone has this disease . . . most of them . . . if not all of them! We need to educate those women who live on their own because they need to live . . . they have no alternative.[58]

Sex as a Survival Strategy

The exchange of sex for survival is not a new theme in feminist writing. Luise White's study of prostitution in colonial Kenya presents a powerful argument that the sale of sex is a form of labor; prostitutes are "sex workers."[59] In *Prostitution and Victorian Society*, Judith Walkowitz asserts that the prostitutes were "not rootless social outcasts but poor working women trying to survive in towns that offered them few employment opportunities and that were hostile to young women living alone."[60] In Uganda, women on their own have been victimized for fear that they *could have* AIDS and that their only means of survival is prostitution. In 1986, teenaged girls and young women were arrested and deported from Masaka District because of such fears.[61]

The fear that single women on their own will spread sexual disease through prostitution is deeply embedded in human history. Its appearance in Uganda in connection with AIDS is no surprise, but these academic observations do not ease the desperate situation of women without male patronage who are forced to find other means of survival. For many women, one of the few strategies possible is the exchange of sex for cash, food, or material goods. Unfortunately, for these women their very means of survival is widely perceived to be one of the main routes of transmission of HIV. The moral condemnation of women is the expression of the hypocrisy of male-dominated society. It obscures the deeper socio-economic forces behind this form of exchange and misses a major "co-factor" in the spread of HIV. Until public health authorities, as well as the wider society, understand clearly what forces Ugandan women to prostitute themselves, the epidemic will be extremely difficult to control.

The Ugandan press abounds with reference to prostitutes spreading AIDS and the necessity to control and eliminate this class of women. Women are trapped by cultural patterns of marriage, inheritance, and land tenure which make it difficult to survive without the patronage of a male. Several prostitutes expressed their views clearly to me: "When you don't have a husband then you are a *malaya* because if a man gives you money you have to accept. If you refuse, where will you get the money for house rent? You accept the money and buy food to feed the children." This 23-year-old woman living with her four children in a rented room in a Kabale slum further explained:

> Maybe you have three or five children and then there comes a good man who sympathizes with you and he says, "Come and sleep with me and I'll give you what you want." You then accept, having seen the way the children are crying because of having nothing to eat. Then you sleep with him and then you get something to give to the children.

An illiterate woman who manages to retain custody of her children and who has either lost a husband or become separated has few options in southern Uganda. Impoverished parents eking out a subsistence living on tiny fragments of land in such an overpopulated region can-

not afford to welcome home a daughter with additional dependents. Many girls seek survival in urban fringe areas like a 17 year old who told me, "I am a malaya. I'm uneducated and can do nothing else." When I asked her if she was concerned about AIDS she articulated a widespread attitude of despair: "What's to fear . . . we all got infected long ago."[63] A woman in a bar sketched out the hard economics of survival: "AIDS kills after about a year, but house rent is required just a few days from today. On top of that, I need lunch tomorrow."[64]

Unattached women like these occasion much hostility from Ugandan society and authorities. There have been calls to ban prostitution and to imprison offenders for six months followed by deportation to their home villages.[65] The District Administrator of Kampala visited a slum in 1990 and again in 1991 to investigate prostitution for himself. In the slum, men survive primarily through petty trade and business while many women brew beer and sell sex. On his first visit, the District Administrator was accompanied by television cameras in hopes of exposing and humiliating women engaged in prostitution. Clearly it was hoped that moral disapproval would effect a change. But during his second visit in 1991, the District Administrator became aware of the many economic pressures forcing women into this trade. Education, while highly prized, is not free in Uganda and many women rent dingy rooms, dubbed "sex-booths," in which they try to earn enough for school fees and food for their children.

Schoolgirls have prostituted themselves for school fees for many decades, as is revealed by a 1957 study of Kampala,[66] although it is widely believed that only recently "the burden of paying school fees . . . traditionally a male responsibility has shifted considerably to women."[67] Ugandan social scientists found in one study that 33 percent of women with children in schools were paying part or all of the school fees and 57 percent of these had difficulties. The somewhat chastened District Administrator who set out to humiliate women in the slum admitted that

> Although the AIDS Control campaign has largely sensitized the elite, educated and religious communities in this country, it has yet to strike a chord among the less privileged in our society. Economic hardships often force poor women to choose between sex for money and starvation.[68]

Women's Burden: Agriculture and AIDS

> About half of the women in the world live and work on farmlands in developing countries and are responsible for 40 to 80 percent of all agricultural production, depending on the country.[69]

In Uganda, as in many sub-Saharan African countries, women underpin the national economy through their agricultural production. Over 95 percent of Uganda's foreign earnings derive from agricultural products and, in spite of the widespread belief that cashcrops are a male preserve, it is women who provide over half the labor.[70] Crucially, however, "men usually control the cash crop marketing and the generated income."[71] Women also cultivate the subsistence crops which feed their children and husbands. Cultivation is labor intensive and few women can afford to employ extra help, a vital factor in farming systems utilizing virtually only a hoe.[72] In four districts as many as 80 percent of the women are unable to employ labor.[73] In 1980 85 percent of cultivated land in Uganda consisted of household plots of less than five hectares and 85 percent of these were cultivated with only a hand hoe

and panga.[74] Another factor affecting production arises in connection with the practice of polygamy. In polygamous societies, women are often reluctant to make capital investments in cultivation or to engage in economic enterprises fearing replacement by another wife.[75]

Agricultural exports for 1992 in Uganda dropped to one quarter of the amount exported in 1991. The explanation given was a combination of drought and "many unfulfilled barter deals."[76] Not mentioned, however, was the much more likely explanation—the impact of AIDS on agricultural production. A Food and Agriculture Organization-funded study of the potential impact of AIDS on agricultural production in Malawi, Rwanda, and Tanzania, has predicted that it will be necessary to switch to less labor intensive crops which will affect household income and nutritional levels. As a consequence, the costs of items requiring cash, such as school fees, medicines, and additional foods, will also become prohibitive.[77]

Conclusion: Women and AIDS

The African kinship system as a form of "safety net" or "social security" is a subject under much scrutiny in connection with AIDS. Until recently, many aid agencies had faith in the strength of the family and clan in Africa to absorb orphans and other dependents caused by AIDS. But this faith is often based on outdated and scanty evidence. Recent studies expose the tenuousness of the so-called support system, and Ugandans themselves suggest cultural changes to cope with the epidemic.[78]

Women's lives in Uganda are difficult with little or no leeway to bear further burdens yet they suffer most the brunt of AIDS morbidity and mortality.

> The disease is spreading very rapidly in impoverished communities which depend on human labour for survival and where the levels of national poverty are already so great that the resources for dealing with the care of the sick and dying and the orphans are already extremely scarce.[79]

As women fall ill and die, not only households, but the whole nation will suffer.

These factors combined with the second-class citizen status of the vast majority of women in Uganda and their lack of opportunity in the labor market forces many of them into prostitution, while millions have no option other than to remain in marriages in which they cannot negotiate sexual relations. It is not surprising that women, crucial to the Ugandan economy, are vulnerable to HIV infection. Nor is it surprising that international agencies and many Ugandans recognize the need to improve the status of women. The question is how to empower women thus enabling them to control their own sexuality, fertility, health, and lives when faced with the social and political cost to men.

Notes

1. *Weekly Topic* (Kampala, Uganda), 12 March 1993.
2. *New Vision* (Kampala daily paper representing government viewpoint), 9 March 1991.
3. *New Vision*, 1 December 1990.
4. *Weekly Topic*, 5 February 1993.
5. *New Vision*, December 1990.
6. Michael Twaddle, "Introduction," in Holger Bernt Hansen and Michael Twaddle, eds., *Uganda Now: Between Decay and Development* (London: James Currey, 1988), 1.
7. Useful analytical categories suggested by Tony Barnett and Piers Blaikie, eds., *AIDS in Africa: Its Present and Future Impact* (London: Belhaven Press, 1992), 86. Afflicted households are those suffering direct

impact of HIV through infected or sick members while affected households are those suffering indirectly.

8. Uganda Ministry of Health, AIDS Control Programme, "Progress on the AIDS epidemic in Uganda," August 1991, Uganda AIDS Commission, Kampala.
9. John Stover of the Futures Group was the analyst who conducted the research. He explained that the twelve million would include AIDS deaths as well as loss of children not born because of AIDS.
10. *Weekly Topic*, December 1990.
11. The Uganda AIDS Commission Bill was passed on 4 December 1991 and includes four directorates: President Museveni; Stephen Kaggwa Lwanga, Director-General (who took office in February 1991 before the commission officially began); Dr. Wilson Kisubi for coordination and program support; Dr. Enoch Rukare for policy and strategy planning; Dr. Romano Adupa for strategy and program monitoring; Mr. Benjamin Mukasa for administration and finance. Dr. John Rwomushana is the Programme Officer. There are ten other employees.
12. The most recent census was completed in 1991.
13. Thirty percent of the total population [5,040,000] is aged five to fourteen.
14. A 1984 study of four districts found the following dependency ratios [based on individuals under age 20]: Busoga:1/3, Masaka:1/4, Kigezi:3/1, Teso:2/1. Carol Jaenson, Josephine Harmsworth, T. Kabwegyere, and P. Muzzale, "The Uganda Social and Institutional Profile [SIP]," unpublished report prepared for USAID/Uganda by the Experiment in International Living, August 1984. The report is available from the USAID office in Kampala. The findings of the 1990 Uganda Household Budget Survey highlight differences between rural and urban households. Rural adults are responsible for more dependents, although urban areas are not far behind.
15. Uganda Ministry of Health, AIDS Control Programme, "Progress on the AIDS epidemic in Uganda," August 1991, 2. It is important to note that the vast majority of AIDS cases remain unrecorded because of underreporting, delays in reporting, and under-recognition. Many people do not have access to medical facilities and even among those who do, most cases of AIDS in Uganda are diagnosed "clinically," that is, without laboratory tests, and thus remain unofficial and escape statistics. The statistics represent only the "tip of the iceberg."

    A sociologist at Kitovu Hospital in Masaka is of the opinion that the keeping of statistics is not a cultural practice in Ugandan societies. She explains that Europeans categorize humans objectively and easily keep lists, inventories, and statistics whereas a Ugandan categorizes humans subjectively making quantification conceptually difficult. Interview of Sister Kay Lawlor, St. Joseph's Hospital, Kitovu, Masaka, Uganda.
16. Males aged 25-29 and females aged 20-24 are the most affected by AIDS in Uganda.
17. Some researchers have reported infection rates among women to be 1.4 times higher than among men. S. Berkeley et al., "AIDS and HIV infection in Uganda: are more women infected than men?" *AIDS* 4(1990): 1237-1242.
18. As of 30 June 1993, a cumulative total of 41,193 clinical AIDS cases had been reported; 91.8 percent were adults over the age of 12 and 8.2 percent were children. It is still assumed that there is gross underreporting and many experts suggest multiplying by six the number of cases actually reported.
19. Report of a Harvard study, *New Vision*, 13 September 1989.
20. A joint project of the British Medical Research Council (MRC) and Overseas Development Administration Programme in collaboration with Makerere University Medical School. Researchers will follow a cohort of 10,000 people.
21. London School of Hygiene and Tropical Medicine, "Magnitude and impact of AIDS in Africa," 3 June 1993 press conference by Dr. Daan Mulder, Director, MRC Research Programme on AIDS, Entebbe, Uganda.
22. The World Bank, *World Development Report 1993: Investing in Health* (Oxford: Oxford University Press, 1993), 238.
23. *Uganda, 1986-1991: An Illustrated Review* (Kampala, Uganda: Fountain Publishers, 1991).
24. United Nations Children's Fund (UNICEF), *Children and Women in Uganda: A Situational Analysis* (Kampala, Uganda: 1989), 54.
25. The World Bank, *Sub Saharan Africa: From Crisis to Sustainable Growth—A Long-Term Perspective Study* (Washington, D.C.: The World Bank, 1989), 264.
26. Stanley Scheyer and David Dunlop, "Health services and development in Uganda," in Cole P. Dodge and Paul D. Wiebe, eds., *Crisis in Uganda: The Breakdown of Health Services* (Oxford: Pergamon Press, 1985), 27-29.

27. In July 1985 the average monthly civil service salary was estimated to be US$21; by 1989 it was US$10 while university professors received US$25. In order to survive, nearly all income earning Ugandans maintain other small businesses and do subsistence cultivation. "The tendency to take up several jobs (especially in the teaching and medical professions) leads to declining standards." Joke Brandt, SNV/Netherlands Development Organization, "Appraisal of Uganda," unpublished report, 1987, 23.
28. The infant mortality rate is calculated on deaths between birth and age one year. The child mortality rate includes deaths between one and five years.
29. World Bank, *World Development Report 1993: Investing in Health*, 208.
30. Ibid. Three point four percent Gross Domestic Product is expended on health. In 1990, foreign aid provided $46 million for health covering 48 percent of all government health expenditure.
31. Barnett and Blaikie, eds., *AIDS in Africa*, 48.
32. *New Vision*, 28 June 1991.
33. C. Robertson and I. Berger, eds., *Women and Class in Africa* (New York: Africana, 1986); Meredith Turshen, *Women and Health in Africa* (Trenton, New Jersey: Africa World Press, 1991); H. M. K. Tadria, "Changes and continuities in the position of women in Uganda," in Paul D. Wiebe and Cole P. Dodge, eds., *Beyond Crisis: Development Issues in Uganda* (Kampala, Uganda: Makerere Institute for Social Research, 1987), 79-90.
34. Tadria, "Changes and continuities," 86.
35. Ibid., first proverb, 85. Christine Obbo, *African Women: Their Struggle for Economic Independence* (London: Zed Press, 1980), second proverb, 8.
36. Henrietta L. Moore, *Feminism and Anthropology* (Minneapolis: University of Minnesota Press, 1988), 45; Jack Goody, *Production and Reproduction* (Cambridge: Cambridge University Press, 1976), 7.
37. Bridewealth consists of instalments, over time, by the family of the husband to the father of the woman. Bridewealth consists of material goods—cows, goats, hens and cash. Its processual nature transforms bridewealth, in effect, into an evolving contract of alliance between two families, not two individuals, and it is not always clear when marriage is completed. When marriages break down, bridewealth payments must be returned and this can be a very complicated affair when marriages have lasted some time.

    In 1992-1993 bridewealth in western Uganda averaged two to four cows (valued at 40,000-50,000 Ugandan shillings/£sterling33-£sterling42), one bull, a number of goats and cash ranging between 100,000-500,000 Ugandan shillings (£sterling83-£sterling400). An educated daughter's bridewealth was 1.5 million Ugandan shillings(£sterling1,250). Interview with BT (initials are used to protect privacy), Kabale, 13 March 1992.
38. *Weekly Topic*, 23 April 1993.
39. D. L. Okwonga in *Weekly Topic*, 23 April 1993.
40. Goody, *Production and Reproduction*, 7. This is characteristic of African hoe-agriculture societies in which the man's property is passed to male members of his kin-group and women do not inherit nor do they receive a dowry at marriage. Instead, bridewealth is paid by male kin of the husband to the male kin of the wife. See Josephine Harmsworth, "The Ugandan family in transition," in Wiebe and Dodge, eds., *Beyond Crisis*, 92. See also Jaenson et al., "Uganda Social and Institutional Profile."
41. Justice E. M. Mukasa Kikonyogo, "Why women accept violence from men with love!" *Weekly Topic*, 25 December 1992. A paper written for the International Association of Women Judges, San Diego, California, 12 October 1992.
42. Ibid.
43. The *Uganda Argus* (newspaper), 17 October 1962. Quoted in Obbo, *African Women*, 13.
44. Pseudonyms will be given to protect the privacy of all informants.
45. Interview with PK, Bukinda, Kabale, 12 May 1990.
46. Interview with DB, Kabale, 1 December 1990. Since the time of the interview in 1990, I have learned that the eldest granddaughter, aged fourteen, has given birth to a child.
47. Christine Obbo, "The social implications of AIDS," *The Courier* (newspaper), March-April 1991.
48. Interview with GK, Kisiizi Hospital, Kabale, 15 December 1990.
49. Interview with Mrs. EZ, Kabale, 14 March 1992.
50. D. L. Okwonga in *Weekly Topic*, 23 April 1993.
51. Interview with BT, Kabale Family Planning Association, 13 March 1992.
52. Interview with Mrs. PG, Rushoroza Diocesan Administration, Kabale, 1 May 1992.

53. Republic of Uganda, Ministry of Health, *Demographic and Health Survey 1988/1989* (Entebbe, Uganda, 1989), 13; Quote from interview with ZN, Lukaya Trading Centre, May 1992.
54. Interview with Mrs. PG, Rushoroza Diocesan Administration, Kabale, 1 May 1992.
55. Interview with PB, Masaka, 9 January 1990.
56. Luise White defines *malaya* as a woman who stays inside her room to which men come seeking sex together with other domestic comforts such as food, bathing, conversation and occasionally a night's rest. Often euphemisms are employed such as "good friend" or "dress maker." Luise White, *The Comforts of Home: Prostitution in Colonial Nairobi* (Chicago, Illinois: University of Chicago Press, 1990), 15. Many of my Ugandan informants who lived in this way told me they made "tablecloths."
57. Interview with NK, Kabale, 13 February 1992.
58. Interview with Mrs. PG, Rushoroza Diocesan Administration, Kabale, 13 February 1992.
59. White, *Comforts of Home*.
60. Judith R. Walkowitz, *Prostitution and Victorian Society: Women, Class, and the State* (Cambridge: Cambridge University Press, 1980), 9.
61. *Weekly Topic*, March 1986.
62. Interview with EK, Bugongi, Kabale, 10 December 1990.
63. Interview with JO, Bugongi, Kabale, 17 December 1990. Andrew Abaho, "Sociological context of AIDS education for behaviour change among the Bakiga," unpublished report of a study for UNICEF conducted in Kabale, February to April 1991. Women in Bugongi told Abaho that they had no alternative to prostitution for survival.
64. *Weekly Topic*, 23 August 1991.
65. *New Vision*, December 1990.
66. Aidan W. Southall and Peter C.W. Gutkind, *Townsmen in the Making: Kampala and its Suburbs* (Kampala, Uganda: East African Institute for Social Research, 1957), 79-80.
67. Abby Nalwanga-Ssebina and Dr. Edith Natukunda carried out a UNICEF funded "Uganda Women's Needs Assessment Survey" in 1988 in the four districts of Hoima, Masaka, Mukono and Tororo. Interview with DB, Kabale, 2 December 1990: "Most women have to pay school fees in the villages because men use their money to drink."
68. *Weekly Topic*, 20 September 1990.
69. S. E. Charlton, *Women in Third World Development* (Epping, England: Bowker, 1984). Quoted in Moore, *Feminism and Anthropology*, 43. See also Esther Boserup, *Women's Role in Economic Development* (London: George Allen & Unwin, 1970).
70. Uganda Ministry of Planning and Economic Development, *Uganda: Population Factors in National Reconstruction and Development* (Entebbe, Uganda: [1989] 1990), 36. In 1987 coffee alone accounted for 90 percent export earnings and close to 40 percent of government revenue. About 83 percent of the labor force is engaged in agriculture.
71. UNICEF, *Children and Women in Uganda*, 77.
72. The few women who can afford to employ labor will find it increasingly difficult to locate available laborers who are also succumbing to AIDS. This was recently reported by an official of the Uganda Commercial Bank who also mentioned, "AIDS as a major factor in the near collapse of the rural farmers scheme" because "many of the beneficiaries have died from the disease." *Weekly Topic*, 29 January 1993.
73. Jaenson et al., "Uganda Social and Institutional Profile."
74. Republic of Uganda, Ministry of Planning and Economic Development, *Uganda: Population Factors* [1989], 36. Twenty-six percent of women own only a hoe. See Jaenson et al., "Uganda Social and Institutional Profile," 172.
75. *Weekly Topic*, 23 April 1993.
76. *Weekly Topic*, 21 February 1992.
77. Sharon Kingman, "Epidemic threatens food supply in Africa," Science and AIDS [Daily conference bulletin of VII International Conference on AIDS (Florence, Italy, 19 June 1991)].
78. Janet Seeley et al., "The extended family and support for people with AIDS in a rural population in South West Uganda: a safety net with holes?" *AIDS Care* 5(1)(1993): 117-122. See also Susan S. Hunter, "Orphans as a window on the AIDS epidemic in sub-Saharan Africa: initial results and implications of a study in Uganda," *Social Science and Medicine*, 31(1990): 681-690.
79. Barnett and Blaikie, *AIDS in Africa*, 5.

Notes on Contributors

Virginia Berridge is Senior Lecturer in History at the London School of Hygiene and Tropical Medicine. She has just completed a book on the policy history of AIDS in the United Kingdom arising out of the work of the AIDS Social History Programme. Her publications include *Opium and the People: Opiate Use in Nineteenth-Century England* (1987) with G. Edwards; "Health and Disease, 1750-1950" in F. M. L. Thompson, ed., *Cambridge Social History of Britain* (1990); *Drugs Research and Policy in Britain: A Review of the 1980s* (1990); and as joint editor and author, *AIDS and Contemporary History* (1993).

Allan M. Brandt is the Amalie Moses Kass Professor of the History of Medicine at the Harvard Medical School and Professor of History of Science, Harvard University. His work centers on the history of disease and on scientific, biomedical, and socio-cultural responses to problems of disease. Brandt is the author of *No Magic Bullet: A Social History of Venereal Disease in the United States* (1987). He recently served on the National Academy of Sciences Panel on "Monitoring the Social Impact of AIDS."

James W. Curran serves as the Centers for Disease Control and Prevention's Associate Director for HIV/AIDS. He coordinates all of the CDC's HIV/AIDS programs throughout eight centers, institutes, and offices, providing scientific and management direction for the agency's surveillance, education, prevention, and basic science and behavioral research activities. Curran organized and led the initial public health investigation into the outbreaks of *Pneumocystis carinii* pneumonia and Kaposi's sarcoma among gay men that would later be termed AIDS, and has been in the forefront of AIDS research, public health response, and prevention ever since.

R. Gordon Douglas, Jr., is President of the Merck Vaccine Division, Merck & Co., Inc. In his current position, he is primarily responsible for the research, development, manufacturing, and marketing of Merck's vaccine products. Prior to joining Merck in 1989, Douglas had a distinguished career as a physician and academician, specializing in clinical infectious diseases. From 1982 to 1989, he was Professor of Medicine and Chairman, Department of Medicine, Cornell University Medical College, and Physician-in-Chief, The New York Hospital. He also served as Head of the Infectious Disease Unit at the University of Rochester School of Medicine. Douglas has published more than 180 scientific papers and is co-editor, with Gerald L. Mandell and John E. Bennett, of the major textbook of infectious diseases, *Principles and Practice of Infectious Diseases*.

Paul Edward Farmer is an anthropologist and doctor who has worked in impoverished villages in Haiti for the past ten years, and is a resident at Brigham and Women's Hospital, Harvard University. With a group of Haitian community activists, he created and runs a rural clinic and hospital and is committed to community development and improved living and health conditions for rural Haitians. His major interests are in the anthropological investigation of HIV and tuberculosis, in the prevention and treatment of infectious and parasitic diseases, and in community-based responses to endemic and epidemic disease. Farmer's interdisciplinary research in medicine and the social sciences has focused on the experience of suffering and its sources in the intersection of poverty, political oppression, powerlessness and pain. He is the author of *AIDS and Accusation: Haiti and the Geography of Blame* (1982).

Anthony S. Fauci is Director of the National Institute of Allergy and Infectious Diseases. He also serves as Chief of the Laboratory of Immunoregulation within NIAID. Fauci has made many contributions to basic and clinical research on the pathogenesis and treatment of immune-mediated diseases. He delineated the precise mechanisms whereby immunosuppressive agents modulate the human immune response. He developed effective therapies for formerly fatal diseases such as polyarteritis nodosa, Wegener's granulomatosis, and lymphomatoid granulomatosis. Fauci has pioneered studies on the immunopathogenic mechanisms whereby the AIDS virus destroys the body's defenses leading to its susceptibility to deadly infections. He has been instrumental in developing strategies for the therapy and immune reconstitution of patients with HIV disease. He is author, co-author, or editor of more than 800 scientific publications, including several textbooks.

Richard Goldstein started out at the *Village Voice* in 1966 as a rock critic, and the "Pop Eye" column he wrote then was considered by many to be the first significant reporting on rock and culture in American journalism. He has continued to work at the *Village Voice* in various capacities since then and is currently the executive editor. In addition to editing and writing five books, he has written articles on mass culture, sexual politics, and associated areas for *Harper's, Artforum, Esquire, Rolling Stone, New York Magazine, Mirabella, Vogue, Utne Reader, Los Angeles Times, Life,* and the *Saturday Evening Post.*

Caroline Hannaway is a Historical Consultant. She edited the *Bulletin of the History of Medicine* (1979-1990) and directed the Francis C. Wood Institute for the History of Medicine, College of Physicians of Philadelphia (1990-1992). She has written extensively on eighteenth- and nineteenth-century French medicine, and has recently produced an exhibit for the National Library of Medicine on "The Birth of Clinical Medicine: Paris, 1794-1848." Her current research is on twentieth-century American medical science. She is co-chair of the AIDS History Group of the American Association for the History of Medicine.

Victoria A. Harden is Historian of the National Institutes of Health and Director of the DeWitt Stetten, Jr., Museum of Medical Research. She has served as co-chair of the AIDS History Group of the American Association for the History of Medicine since the Group's founding. In 1989, with Guenter Risse, she organized the group's first conference and co-edited the volume of conference proceedings, *AIDS and the Historian.* Harden is the author of *Inventing the NIH: Federal Biomedical Research Policy, 1887-1937* and *Rocky Mountain Spotted Fever: History of a Twentieth-Century Disease* and the editor, with Harriet R. Greenwald, of *NIAID Intramural Contributions, 1887-1987.* Currently, she is conducting

oral histories to document the NIH response to AIDS and also pursuing research on the history of twentieth-century biomedical research instruments.

C. Everett Koop was sworn in as Surgeon General of the United States Public Health Service on 6 November 1981. He served in that capacity until 1 October 1989. Before that, he was Professor of Pediatric Surgery and of Pediatrics at the University of Pennsylvania and was Surgeon-in-Chief of the Children's Hospital of Philadelphia.

Ruth Kulstad worked on four journals (in physics, chemical engineering, and veterinary science) at Pergamon Press, Oxford, England, before coming to the United States in 1962. She then collaborated on an information storage and retrieval project for chemists and agronomists at the Sulphur Institute, Washington, D.C., and subsequently joined the editorial department of *Science* (1963-1965). From 1965 to 1976 she worked on publications in Venezuela, Haiti, and Morocco, and then rejoined *Science* (1976-1988). She went to *The New Biologist* (1989-1992) and then became managing editor of *Clinical Chemistry*. She is the editor of *AIDS: Papers from Science, 1982-1986* (1986) and of *AIDS 1988: Papers Presented at the AAAS Annual Meeting* (1980).

Maryinez Lyons is a Research Fellow at the Institute of Commonwealth Studies, University of London and an Honorary Research Fellow at the London School of Hygiene and Tropical Medicine. She specializes in the history of disease and medicine in sub-Saharan Africa and is currently researching the social history of AIDS in Uganda. Her publications include *The Colonial Disease: A Social History of Sleeping Sickness in Northern Zaire, 1900-1940* (1992); "African Trypanosomiasis (Sleeping Sickness)," in Kenneth F. Kiple, ed., *The Cambridge World History of Human Disease* (1993); "The Power to Heal: African Medical Auxiliaries in Colonial Belgian Congo and Uganda," in Shula Marks and Dagmar Engles, eds., *Contesting Colonial Hegemony: State and Society in Africa and India, 1858 until Independence* (1994); "Public Health in Colonial Africa: the Belgian Congo, 1900-1960," in Dorothy Porter, ed., *Health and the Modern State* (1994).

Anne Marie Moulin is Directeur de Recherche, Histoire des Sciences, Institut National de la Santé et de la Recherche Médicale, Paris, France, and associate professor of history at the Medical School of the University of Geneva. She was trained both as a philosopher and as a physician. As a parasitologist, she has worked in Central Africa and in the Arab world. She has published on the history of immunology, *Le Dernier Langage de la médecine: histoire de l'immunologie de Pasteur au SIDA* (1991) and a number of articles. She has coedited a volume *Science and Empires* for Boston Studies in the Philosophy of Science (1992). Moulin is currently writing a book on the history of the Pasteur Institute, *The Pasteur Institute Between the Two World Wars*, and has forthcoming "The transformation of the International Sanitary Order," in Paul Weindling, ed., *International Public Health Organizations between the Two World Wars* (1994).

June E. Osborn was on the Medical School faculty at the University of Wisconsin from 1966-1988. She then joined the faculty of the University of Michigan where she was Dean of the School of Public Health from 1984-1993 and continues as Professor of Epidemiology in the School of Public Health and Professor of Pediatrics and Communicable Diseases in the Medical School. She has served as advisor in many contexts to the U.S. Public Health Service, the World Health Organization, and private foundations. From 1989-1993 she was

chairwoman of the U.S. National Commission on AIDS, a group mandated by Congress to advise both the legislative and executive branches of the U.S. government on public policy issues raised by the AIDS epidemic.

John Parascandola is Historian for the United States Public Health Service. In 1969, Parascandola joined the University of Wisconsin faculty in history of science and history of pharmacy. In 1983, he became Chief of the History of Medicine Division of the National Library of Medicine in Bethesda, a position that he held until moving to his current job in 1992. Parascandola's research interests have focused on the history of modern biomedical science, and he is the author of a book on *The Development of American Pharmacology: John J. Abel and the Shaping of a Discipline* (1992).

Mark D. Smith is Executive Vice President of the Henry J. Kaiser Family Foundation and has responsibility for the Foundation's Poverty and Health Program. Smith is also a member of the clinical faculty of the University of California at San Francisco. Prior to joining the Kaiser Family Foundation, Smith was Associate Director of the AIDS Service and Assistant Professor of Medicine and of Health Policy and Management at the Johns Hopkins University. Smith has been widely involved in AIDS issues and served as Executive Director of the Philadelphia Commission on AIDS from 1987-1988. He currently serves on the Food and Drug Administration Antiviral Drugs Advisory Committee and chairs the Centers for Disease Control and Prevention Advisory Committee on the Prevention of HIV Infection. He has published and lectured on AIDS and health care financing, ethical issues and the impact of AIDS on minorities, and AIDS screening, public education and research.

James Harvey Young, Charles Howard Chandler Professor Emeritus of American Social History, Emory University, has devoted his research career mainly to the history of American food and drug regulation and the history of health quackery. His quackery books include *The Toadstool Millionaires*, *The Medical Messiahs*, and *American Health Quackery: Collected Essays*, the last of which contains a chapter on "AIDS and Deceptive Therapies." His books on regulation are *American Self-Dosage Medicine* and *Pure Food: Securing the Federal Food and Drugs Act of 1906*, and he is working on a study of how the 1906 law was enforced until replaced in 1938.

Index

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